Exhibit H

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION — MDL No. 2875

This Document Relates to All Actions

_____/

VIDEOTAPED
DEPOSITION OF: KALI PANAGOS, PHARM.D., R.PH
DATE: JANUARY 21, 2022
TIME: 9:32 a.m. - 5:52 p.m.
TAKEN BY: DEFENDANT
PLACE: RIVERO MESTRE LLP
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MIAMI, FL 33134
REPORTED BY: CHELSEA HLAVACH, NOTARY PUBLIC, STATE OF FLORIDA

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I N D E X

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E X H I B I T S

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S T I P U L A T I O N S

It is hereby stipulated and agreed by and between counsel present for the respective parties, and the deponent, that the reading and signing of the deposition are hereby reserved.

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P R O C E E D I N G S

* * * * *

THE VIDEOGRAPHER: Good morning. We are going on the record at 9:32 a.m. on January 21st, 2022.

This is Media Unit Number 1 of the video recorded deposition of Kali -- Dr. Kali Panagos. This deposition is being held at 2525 Ponce de Leon Boulevard, Suite 1000, in Miami, Florida.

My name is Javier Ordonez and I am the videographer. The court reporter is Chelsea Hlavach; both from Veritext. Will the court reporter please swear in the witness?

THE COURT REPORTER: Can we have counsel please state their appearances?

THE VIDEOGRAPHER: Oh, can counsel please state your name and who you're -- I'm sorry. State your appearance and who you represent.

MS. ISIDRO: Nilda Isidro from Greenberg Traurig on behalf of Teva.

MR. KERNER: Glenn Kerner from Greenberg Traurig also on behalf of Teva.

MR. HANSEL: Greg Hansel from Preti Flaherty on behalf of Maine Automobile Dealers Association.

MR. WHARTON: Hi. Charlie Wharton on behalf of Plaintiffs.

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MS. WHITELEY: Conlee Whiteley on behalf of Plaintiffs.

MR. HANSEL: Before we go on the record further, I guess I have a couple of preliminaries. First, Jorge Mestre is also here, Chelsea, on behalf of the Plaintiffs.

And I see I'm being asked on the Zoom to agree that this be recorded on Zoom, and I don't think that's necessary because we have a videographer and a court reporter. So I would request that the Zoom not be recorded.

MS. ISIDRO: The Zooms, I believe, have been recorded at prior depositions, and in the event anyone on Zoom asks questions, et cetera, that's -- that's part of the purpose of -- of the Zoom recording, is my understanding.

MR. HANSEL: That would also be audible in the room and would be picked up on the video, the videographer, the court -- the official videographer, as well as by the court reporter.

Is that really necessary?

MR. KERNER: Well, let me just ask you a quick question. My understanding is that the prior depositions have all been recorded on Zoom as well, and this is for you folks and anybody actually on Zoom

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right now, have there been any objections to the depositions being recorded on Zoom or has there been any agreement for this litigation to have the depositions recorded on Zoom? Because that was my understanding, but I'm asking the group.

MS. ISIDRO: And further --

MR. COTES: Glenn, it's Greg -- it's Greg Cotes. I mean, I've been on dozens and dozens of these in the past six months and I get that recording message every single time and no one's ever said a word about that.

MS. ISIDRO: Yeah. I would also add that Plaintiffs have -- have raised objections to the number of folks in the room in person, and this was something that was discussed at the recent status conference, and that is also part of the reason why there is the Zoom setup, just in light of the pandemic and concerns about safety that have been raised by Plaintiffs, just as much as by anyone else.

And so, again, I don't see the -- the problem with recording the Zoom consistent with all of that.

MR. HANSEL: Okay. All right. In that case we'll -- we'll allow it.

MS. ISIDRO: Thank you.

THE COURT REPORTER: Okay. Will you raise your right hand, please?

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Do you swear or affirm the testimony you are about to give in this matter will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: I do.

KALI PANAGOS, PHARM.D., R.PH,

having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. ISIDRO:

Q. Good morning, Dr. Panagos.

A. Good morning.

Q. My name is Nilda Isidro. I'm with the law firm of Greenberg Traurig and I represent Defendant, Teva.

A. Uh-huh.

Q. We're just meeting for the first time this morning, correct?

A. Yes, we are.

Q. Can you please state your full name for the record?

A. My full name is Dr. Kali Panagos.

Q. And what is your current professional address?

A. My current professional address is 105 Down Court, Windermere, Florida -- Florida.

Q. Thank you. Where do you currently reside?

A. New York.

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Q. Have you ever been deposed before?
A. No, I have not.
Q. Okay. So I'll just go over a few ground rules on how -- on how this works --
A. Sure.
Q. -- since this is your first deposition.
As you can see there's a court reporter to your right who's taking down everything that we say.
A. Uh-huh.
Q. So for that reason, it's very important that you answer verbally, meaning yes -- saying yes or no rather than nodding your head or saying --
A. I understand.
Q. -- uh-huh or huh-uh, and for that same reason, it's important that -- that we not talk over each other, right? So that you wait that -- until I finish my question before you start to answer, and I'll do the same. I'll try to wait until you finish your answer before I start the next question, just so that the court reporter isn't trying to take both of us -- what both of us are saying down at the same time. Is that all right?
A. That's right.
Q. Great. As -- as you've seen this morning, there are some folks who are also on Zoom and so there's that setup as well. There you may hear -- you may hear

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objections or something coming from Zoom. You may also later today get questions from folks on -- on -- on the Zoom.
If at any time you don't understand my question, please let me know. If you don't hear my question, please let me know. If -- however, if you do answer my question, I'm -- I'm going to take that to mean that you understood my questions. Is that fair?
A. Yes.
Q. Okay. If at any time you need to take a break, just let me know and -- and we can do that. I would just ask that if there's a question pending, that that question be answered before we go on a break.
A. Okay.
Q. Do you have any questions about the -- how this -- about how -- the procedures or how this will work today?
A. Not at this time.
Q. Okay. And as you know you're here to testify under oath. Is there any reason that you would not -- you would not be able to give truthful and accurate testimony today?
A. No.
Q. You're not on any medications that might interfere with your ability to testify or anything like

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that?
A. No.
Q. Okay. And do you want to read and sign this deposition?
A. Sure.
Q. Okay. Now, Doctor, you're appearing here today pursuant to a notice of deposition; is that right?
A. Yes.
Q. Okay. We're going to go ahead and mark that notice of deposition as Exhibit 1. And, again, as I mentioned, because of the Zoom, someone's going to be loading these exhibits up on the Zoom as well, so we may just give a little bit of a pause when we mark an exhibit so that they can get caught up as well.
(Exhibit No. 1 was marked for identification.)
All right. Doctor, have you seen this document before?
A. No.
Q. Okay. I'm going to ask you to take a look at Page 6. There are a number of requests there. And just if you could take a look at those and let me know, did anyone ask you whether you had any of these documents that are requested here in your possession?
MR. HANSEL: I'm going to object on grounds of work product privilege to any requests for

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communications between counsel and the witness as, you know, we have also responded to this request in writing, as you know.
MS. ISIDRO: I'll rephrase my question.
BY MS. ISIDRO:
Q. Prior to the deposition today, did you check whether you had any of the documents that are listed in these requests in your possession?
A. Yes.
Q. Okay. We're going to go through them one by one.
A. Sure.
Q. And -- and we'll talk about each one. So the first one is your current up-to-date resume or CV. There was a CV attached as an exhibit to your report, correct?
A. Correct.
Q. Is that your current CV?
A. Yes.
Q. Since -- since producing your report, have -- have there been any updates to the information on that CV?
A. No.
Q. Okay. Let's go ahead and mark that CV as Exhibit Number 2 and then we'll go through later on the rest of the items on this list.
(Exhibit No. 2 was marked for identification.)
Okay. Doctor, so it notes on your CV that you

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received a bachelor of science from St. John's University in 1997; is that right?
A. Yes.
Q. What was your major?
A. Biology.
Q. Did you have any minors?
A. Computer science.
Q. How long did it take you to complete that bachelor of science?
A. Four years.
Q. And then after that you pursued a second bachelor's degree; is that right?
A. Yes.
Q. That was from St. John's University in 2000?
A. Yes.
Q. What was your major then?
A. Pharmacy.
Q. And did you have any minors at that time?
A. No.
Q. How long did it take you to complete that bachelor's degree?
A. That was completed in 2000.
Q. When did you -- when did you begin pursuing that bachelor's degree?
A. In '97.

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Q. Okay. And -- and then you received a doctorate from Shenandoah University in 2006?
A. Yes.
Q. That was also in pharmacy?
A. That was a doctorate in pharmacy, yes.
Q. Okay. And when did you begin pursuing that doctorate?
A. Two years prior to the graduation date.
Q. Have you had any other formal education beyond those degrees that we've just discussed?
A. No.
Q. Okay. So in 2002 you joined the Long Island University's faculty; is that right?
A. Yes.
Q. And you were on that faculty until 2009?
A. Yes, I was part of the faculty and administration till 2009.
Q. What -- what was your first role within Long Island University's faculty and administration?
A. Director of pharmacy services.
Q. And how long did you hold that position?
A. I held that until, you know, 2009.
Q. Okay. What were your roles and responsibilities under that title?
A. My roles and responsibilities were to oversee the

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curriculum of the pharmacy program, the pharmacy advisors reported to me with regards to students -- student advisement for coursework in the pharmacy program, and I also evaluated student progress for remaining and -- within the program as well.
Q. Okay. And did you have any other titles or roles within the Long Island University?
A. Yes, I served as an adjunct faculty in the department of social sciences.
Q. From --
A. In the pharmacy program.
Q. From what year to what year?
A. 2000 and -- jeez. I was -- 2005 about until 2009.
Q. Okay. Did you teach classes as part of that role?
A. I certainly did.
Q. What classes did you teach?
A. I taught pharmacy orientation, which is an introduction course to pharmacy. I also taught or was part of the recitation courses, which are laboratory type courses in the social sciences division of pharmacy program.
Q. Okay. Any other courses that you taught?
A. No.

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Q. And other than these two roles that we've just discussed, did you have any other roles or titles within the Long Island University?
A. No.
Q. You're currently a registered pharmacist in the State of New York?
A. Yes, I am.
Q. Are you registered or licensed as a pharmacist in any other state?
A. No.
Q. Do you have any other certifications -- professional certifications or qualifications?
A. I do.
Q. What are they?
A. I have an immunizer certification; I am certified in first aid or CPR for infant, child, and adults; I am also certified as an MTM pharmacist; and I also have a New York State Department Adjuster License as well.
Q. Okay. You mentioned an immunizer certification. What does that -- what does that mean?
A. That means I am permitted to administer immunizations to patients.
Q. And what is an MTM pharmacist?
A. Medication therapy management.
Q. What -- what does medication therapy management

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entail?
A. It entails being able to counsel patients on their -- the drugs that they're on and their overall profile and provide them guidance for compliance and adherence.
Q. What do you mean by compliance and adherence?
A. So that they know how to properly take their medication, what the medication is for, and review with them the -- their overall drug profile.
Q. And then you also mentioned New York State Department Adjuster. What does that entail?
A. At this time I don't have any requirements that it -- that I'm required for that, so it's there, but I don't have any requirements for it.
Q. What does a New York State Department Adjuster do?
A. That is used in the managed care field or in the pharmacy management or if you needed to -- it's more on the business side. So it's not directly patient care. It's on the business side of the pharmacy.
Q. What does that mean, more on -- more on the business side? What types of things?
A. The organization I was employed with, Broadreach Medical Resources, it was beneficial to them if I had this adjuster license.

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Q. In what way was it beneficial?
A. To adhere with requirements by New York State for the -- their type of business.
Q. What responsibilities did you have with that employer as -- as an adjuster?
A. My responsibilities to that employer were in the capacity of a clinical pharmacist and director of clinical operations, as well as client oversight as well.
Q. Okay. I'm just trying to understand how the -- the New York State Department Adjuster certification comes into play.
A. Uh-huh.
Q. What it allows you to do that you wouldn't be able to do if you had -- if you did not have that certification.
A. It allows the organization to adhere with the requirements of New York State by having an adjuster's license -- an employee with an adjuster's license on staff.
Q. Now, you also mentioned certain clinical affiliations in your CV?
A. Yep.
Q. And -- and those -- one of those is with Hospital of Special Surgery, correct?
A. Correct.
Q. You mention in your report that you have a

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clinical affiliation in pain management and anesthesia at the Hospital for Special Surgery, correct?
A. That is correct.
Q. What does that position entail?
A. That position required me to participate and understand the functions of anesthesiology and pain management of patients as it regards to their procedures that they were -- with regards to their procedures that they were having and work closely with the anesthesia team and pain management -- management team for management of that patient while they were in the hospital.
Q. Did you have any sort of patient facing role in that position?
A. The patients were in surgery, so I was in the surgery room with the anesthesiologists and then we would visit the patient in the post-op.
Q. Okay. You didn't -- you didn't prescribe any medication or anything like that, correct?
A. No, I did not.
Q. Do you have the ability to prescribe medication?
A. No, I do not.
Q. Okay. And during what time did you have that clinical affiliation?
A. That was during my time at St. John's pursuing the pharmacy -- my bachelor's of pharmacy degree.

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Q. Okay. And then you also list a clinical affiliation with Bellevue Medical Center.
A. Yes.
Q. And during what time did you hold that clinical affiliation?
A. That clinical affiliation was done during my time pursuing my doctorate degree in pharmacy.
Q. Okay. And what was your role with Bellevue Medical Center?
A. My primary role was participation in the lipid and anticoagulation clinics, participation with the medical and pharmacy teams there to manage patients.
Q. And then you've also listed a clinical affiliation with Northwell Health University.
A. Correct.
Q. During what time frame did you hold that clinical affiliation?
A. That affiliation was done during my time at St. John's University pursuing the bachelor's of pharmacy degree.
Q. And what was your role with Northwell Health?
A. That was an internal medicine rotation with a focus on diabetes, participating in medical rounds and with physicians and pharmacists to manage patients with different diagnoses and conditions for which they were in

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the hospital.
Q. And, finally, you list as -- under clinical affiliations, advisory panel member, AMGEN for Repatha?
A. Correct.
Q. During what time frame did you hold that position?
A. 2019.
Q. And what were your roles and responsibilities as an advisory panel member?
A. I was asked to participate in the advisory panel for evaluation of Repatha and discussion about the use of the drug and -- in all capacities.
Q. What type of drug is Repatha?
A. Repatha is a lipid lowering drug or hypercholesterolemia drug intended for certain populations that meet the criteria for intended use.
MR. MESTRE: If you're taking a pause, I just wanted to make my appearance. Jorge Mestre on behalf of the Plaintiffs. And I also wanted to make sure that we're not recording on the Zoom, correct?
MR. KERNER: We are and we had that discussion.
MR. MESTRE: Oh, we did?
MS. ISIDRO: We had that discussion already. Yes.
MR. MESTRE: Okay. Okay.

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MR. KERNER: And your co-counsel noted your appearance earlier as well.
MR. MESTRE: Thank you.
BY MS. ISIDRO:
Q. Dr. Panagos, you worked as a pharmacist at Walgreens in New York from 2000 to 2015; is that correct?
A. That is correct.
Q. Were you the lead pharmacist during that time?
A. I was a staff pharmacist.
Q. Okay. Besides staff pharmacist, did you ever have any other roles with Walgreens?
A. No.
Q. What were your duties and responsibilities as a staff pharmacist?
A. To manage the pharmacy, so that's all aspects of the pharmacy at the time where I'm assigned, my hours of work, and so that includes the prescriptions, filling the prescriptions, reviewing, filling, dispensing, and counseling the -- the prescriptions that are coming in and for the patients that are coming in.
I also supervise the technicians that are working in the pharmacy during that time. They fall under my supervision, including the interns that are on shift at the same time as I am. I'm also responsible that the drug product is the correct drug product is being filled and

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verifying that that is the right medication, the right patient, and ensuring that there aren't any contraindications for the -- for the patient so.
Q. And during part of this same time period you also worked at Broadreach Medical Resources; is that right?
A. Correct.
Q. That was from 2008 to 2018?
A. Correct.
Q. And what was your role at Broadreach?
A. I had several roles -- roles there. I was a clinical pharmacist and then became the director of clinical operations and also the head of client management as well.
Q. From what year to what year were you a clinical pharmacist at Broadreach?
A. The entire time.
Q. And from what year to what year were you director of clinical operation?
A. As it states in my CV, 2008 through 2018.
Q. So for the full time period?
A. Yes.
Q. Okay. And from what year to what year were you head of account services and client management?
A. It was a couple years later so 2009 or 2010. Shortly thereafter.

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Q. Okay. So within a couple of years of starting at Broadreach through the end of your time there?
A. Correct.
Q. Okay. What was the split on your time between Broadreach and Walgreens during this time frame?
A. I began my time with Broadreach initially part-time.
Q. Uh-huh.
A. And I was also part-time or per diem -- well, part-time with Walgreens at that time.
Q. What were your duties and responsibilities as a clinical pharmist- -- pharmacist at Broadreach?
A. My duties included review of prior authorization requests, collaboration with prescribers as needed on behalf of those requests, collaboration with -- or outreach to patients as needed on behalf of those requests. So review of the prior authorization, completing that request, documenting the results or the findings, tracking that, and communicating appropriately.
Q. What were your roles and responsibilities as director of clinical operations at Broadreach?
A. My roles and responsibilities as clinical operations included ensuring that management of the formulary, management of the prior authorizations, management of every clinical aspect with regards to the

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prescription benefit was done efficiently in a proper workflow.
Q. And what were your roles and responsibilities as head of client services and account management at Broadreach?
A. My roles and responsibilities included advising patient -- clients on all aspects of their pharmacy program, which includes their formulary, their plan design, drugs covered and not covered, and providing them with guidance on how to best do that.
Q. Your CV states that you developed industry exclusive prescription indemnity/reference based program during your time at Broadreach. Can you tell us more about that, what that entailed?
A. That is a prescription type program that is -- takes a subset of drugs and applies -- creates a -- a plan that clients or employers may choose if it's appropriate for their employees as a prescription drug offering. It is structured to allow kind of a different option for employers to take for prescription benefits.
Q. And what was your role in developing that program?
A. My role in developing that program included choice of the medications that would be part of the product offering and that includes both brands and generics, and

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how those medications would be structured within that program for tiering or payments, et cetera.
Q. Your CV also states that you designed evidence based market competitive clinical programs with documented ROI. Can you tell us what that refers to?
A. Sure. Clinical programs are a part of a pharmacy benefit offering and they are designed based on evidence based guidelines, which are accepted in the healthcare community as how you -- patients would be treated according to the conditions that they have. So when you create a clinical program, you do so on clinical merit but in the -- you structure it on clinical merit, but you also incorporate other components essential to the prescription drug benefit to help clients manage their population and -- and it's linked to the formulary.
Q. You referenced some evidence-based guidelines. Are there specific evidence-based guidelines that you used in putting together those programs?
A. Yes.
Q. Which ones?
A. There were many.
Q. Can you give some examples?
A. Asthma, diabetes, cardiovascular, just to name a few. There are many.
Q. So when you say asthma, what does that refer to

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in terms of an evidence-based guidelines?
A. The guidelines set forth by the medical community for treatment of a patient with a diagnosis of asthma.
Q. And for the other conditions that you mentioned, is it the same --
A. The same.
Q. Okay. Your CV also states that you manage integration of data across medical and prescription, including population, health, and enrollment analytics?
A. Correct.
Q. Can you tell us more about what that entailed?
A. Yes. My role included review and analysis of the data that -- both on the prescription side and where available on the medical side and being able to evaluate that on behalf of our clients.
Q. What do you mean by the data on the prescription side?
A. Claims data.
Q. And what do you mean by the data on the medical side?
A. Likewise.
Q. Where would you get that data?
A. The data would come from the PBM or the medical carrier.
Q. And finally your CV states that you served as

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subject matter expert on all PBM clinical drug and specialty items.
A. That is correct.
Q. What did you mean by served as a subject matter expert on PBMs?
A. So for our clients and -- I was the person who they would come to for questions about determining -- any question on PBM, actually. So I served as a subject matter expert to advise on PBM and yeah.
Q. And those clients were -- not -- not specific names, but, you know, what -- what type of entities --
A. Self-insured --
Q. -- were those clients?
A. -- clients, self-insured employer groups.
MR. HANSEL: Please remember to let her finish her question before you begin your answer.
THE WITNESS: Okay. Thank you.
BY MS. ISIDRO:
Q. And what do you mean by served as a subject matter expert on clinical, drug, and specialty items?
A. Again, I would provide guidance and advisement on drugs that are -- were on the formulary or even not on the formulary. I'd provide the -- would answer any questions related to those drugs.
Q. What does the clinical refer to?

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A. The clinical refers to the medication and the use of the medication from my background and experience as a pharmacist of being able to provide that thought process around the discussion of the medication.
Q. And what do you mean by specialty items?
A. Specialty medications are part of a formulary and they are -- there's -- there's no universal accepted definition for specialty but they're -- tend to be for more complex conditions.
Q. Is that what you're referring to when you use that term in your CV?
A. Correct.
Q. Okay. You also spent it seems like a year or maybe less than a year at Smith Rx in San Francisco; is that right?
A. That is right.
Q. How -- how -- what is the precise amount of time that you spent at Smith Rx?
A. I think it was from February to December. Yeah.
Q. What was your role or roles within Smith Rx?
A. Director of clinical services.
Q. That was the only role you held there?
A. Yes.
Q. What were your -- your responsibilities under that role?

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A. To set up the pharmacy benefits with regards to formulary, prior authorization, reviews to ensure that those were done appropriately and manage the formulary.
Q. Why did you leave that position?
A. There are several reasons. One, distance from my home.
Q. Your home was in New York at that time?
A. Correct.
Q. What were some of the other reasons?
A. Primarily distance from my home.
Q. And you've been on the Council of Strategic Healthcare Advisors since 2018?
A. Yes.
Q. What are your roles and responsibilities there?
A. They call upon my expertise as needed for cases or surveys, clinical related items for which they deem my qualification's appropriate for response.
Q. Who are you advising in that role?
A. Whatever the particular project at that time calls for, who -- whomever that may be.
Q. What -- are these -- are these all different types of business entities?
A. It could be.
Q. What else could it be?
A. It could be other healthcare professionals, industry experts, industry colleagues. Yeah.

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Q. You're the founder of AristaRx Wellness; is that right?
A. That is right.
Q. And you began that in 2018 as well?
A. Correct.
Q. What is AristaRx Wellness?
A. AristaRx Wellness is my LLC that I created.
Q. What does -- what services does AristaRx Wellness offer?
A. Pharmacy benefit consulting.
Q. And to whom do you offer that pharmacy benefit consulting?
A. To primarily self-insured employer groups but could be any group that needs pharmacy benefit consulting.
Q. Do you have any employees?
A. No.
Q. Are you the sole member of that LLC?
A. Yes.
Q. And what are your duties and responsibilities within AristaRx Wellness?
A. To provide pharmacy benefit consulting to my clients.
Q. Is that still an active company?
A. Yes.

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Q. And the business address that you gave earlier here in Florida, is that for AristaRx Wellness?
A. No.
Q. Okay. What entity was that address for?
A. ARMSRx.
Q. ARMSRx. And you've been with ARMSRx since 2019?
A. Yes.
Q. What is -- what roles have you held within ARMSRx?
A. Senior vice president and executive vice president.
Q. And during what time frame were you senior vice president?
A. 2019 through 2021, as listed on my CV.
Q. And executive vice president during what time frame?
A. 2021 till present.
Q. Okay. What were your roles and responsibilities as senior VP?
A. To provide advice and guidance to our clients with regards to their pharmacy benefit program, all aspects of their pharmacy benefit program.
Q. And what are your roles and responsibilities as executive vice president?
A. To provide advisement and guidance to our clients

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with respect to their pharmacy benefit program, all aspects, and I also oversee or have individuals within our organization who report up to me.
Q. Okay. So you didn't have individuals who reported up to you as a senior VP?
A. I -- right.
Q. Okay.
A. They -- they report up to me now.
Q. Okay. Was that the only way in which your role changed from senior VP to executive VP?
A. Yes.
Q. How many people report to you as EVP at ARMSRx?
A. Two.
Q. And what are their roles?
A. They are in account management and PBM operations.
Q. Doctor, you mention in your report that you have 20 years of experience, half of which has been dedicated to the managed care and pharmacy consulting industry overseeing clinical development, overall PBM operations, and client services/management, working primarily with self-insured clients, third-party administrators, and TPPs; is that right?
A. That is right.
Q. What is a TPP?

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A. A third-party payer.
Q. And can you describe what a third-party payer is or does?
A. They are responsible for reimbursement or management of the health care claims, including the prescription benefit.
Q. And how, if at all, is a TPP different from a self-insured employer?
MR. HANSEL: Object to the form.
A. Could you be more specific?
BY MS. ISIDRO:
Q. Are there any ways in which a TPP differs from a self-insured employer?
A. There could be.
Q. What are some of the ways in which they could differ?
A. Could you be more specific?
Q. You said there could be differences, so I'm just asking you to elaborate on that.
What are some of the differences that could exist?
A. Third-party payers are responsible for the management and reimbursement of the healthcare claims, including the prescription benefit. Self-insured employers would also be responsible in that same capacity but within

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the confines of their organization.
Q. Okay. What is a TPA?
A. Third-party administrator.
Q. What does a third-party administrator do?
A. They would administer the benefits, you know, on behalf of an entity or a group.
Q. And how does that differ from a TPP, if at all?
A. So the third-party payer has ultimate responsibility for -- at risk for those claims. A TPA will manage the claims processing and the functions associated with the benefit but may not have ultimate responsibility or at risk for the claims.
Q. Okay. Now, I see you have a few documents in front of you right now. One of them is Exhibit 1, another one is Exhibit 2, but it looks like you might have a few other documents as well; is that right?
A. Yes.
Q. What are the other documents that you have in front of you?
A. My statement, my opinion, my expert report.
Q. Okay. Anything else that you have in front of you right now?
A. Not document-wise.
Q. Okay. And this copy of your expert report is one that you've brought with you today, yourself?

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A. Yes.
Q. Okay. What is the nature of your work with TPPs?
A. The nature of my work in my role or as a pharmacy benefit consultant -- consultant is to advise on the benefits in all aspects, including formulary, design, and formulary ongoing management, utilization management programs, plan design updates, and -- and all functions related to the pharmacy benefit program.
Q. Do you have any experience with P&T committees?
A. I do.
Q. What is the nature of your experience with P&T committees?
A. Throughout my -- my career as a pharmacist, being intimately familiar with P&T committees is -- and understanding what their function is, has been integral in all aspects of my career.
I have reviewed countless minutes from P&T committees. I do that on an ongoing basis to keep track of, if you will, what the progress is and what the functions and what -- the ongoing developments of the P&T committee, and so I'm -- you know, I'm very familiar with what they do and I have, you know, visibility into the P&T committees with whom my clients are engaged with, are involved with.
Q. How do you obtain these minutes from P&T

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committees?
A. I request them.
Q. From whom?
A. Whomever the P&T committee is with.
Q. And what -- what entities have you requested P&T committee's minutes from?
A. PBMs and health plans.
Q. Which specific ones?
A. That's confidential information.
Q. Why is that confidential information?
A. It's tied into the clients that I provide counseling -- consulting for.
Q. In connection with which company or which of your roles?
A. My current role at ARMSRx.
Q. Only at ARMSRx?
A. Yes.
Q. Have you ever been a TPP employee?
A. No.
Q. Have you ever been a member of a P&T committee?
A. No.
Q. Do you consider MSP to be a TPP?
A. No.
Q. And is it possible sometimes for both a TPA and a TPP to be involved in processing a particular claim?

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MR. WHARTON: Can I hear that question again, please?
MS. ISIDRO: Can you read it back, please?
(The requested portion was read back.)
A. TPAs manage the claims. They are not processing claims.
BY MS. ISIDRO:
Q. Who -- who does the pharmacy expect payment from among a TPA or a TPP?
A. It depends on the structure of the arrangement and who's ultimately -- oh -- responsible for the payments.
Q. So sometimes the pharmacy might expect payment from the TPA first, right?
A. Could you be more specific?
Q. You mentioned it depends on the structure of the particular arrangement, correct?
A. Correct.
Q. Are there sometimes arrangements where the pharmacy might expect payment from the TPA first?
A. That wasn't the focus of my opinion that I'm rendering here today, but to answer the question, it could be.
Q. In your experience with claim adjudication platforms, would both the TPA and the TPP be listed in the claims data?

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A. No.
Q. Which would be listed?
A. Standard industry claims data for prescriptions would list the client as part of, you know, the fields, the client -- whoever the client is.
Q. And would the client -- am I understanding correctly that the client would be either the TPA or the TPP?
A. If you're asking with regards to claims data, the information within the industry claims data extract would include the client that is have -- that is receiving the prescription benefit. So it's tied directly into the client, whoever that entity is.
Q. Okay. So it may not be possible from that information alone to tell whether the third party in each claim is a TPP or a TPA?
A. From that data alone, no.
Q. Okay. Dr. Panagos, you also list on your CV certain professional organizations that you're a member of; is that right?
A. Yes.
Q. You're a member of the American College of Healthcare Executives?
A. Yes.
Q. When did you first become a member?

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A. 2019.
Q. And you're still a member currently?
A. Yes.
Q. What is required to become a member of that organization?
A. The requirements are listed on the website. There are certain qualifications and criteria that you must meet, and I don't recall them all at this moment.
Q. Okay. Do you --
A. But they are listed there.
Q. Do you recall any?
A. Must be a pharmacist in good standing or a healthcare professional in good standing.
Q. Okay.
A. Uh-huh.
Q. And you're also a member of the Academy of Managed Care Pharmacy; is that right?
A. Yes.
Q. When did you become a member of that organization?
A. When I was in pharmacy school.
Q. And you're still a member currently?
A. Yes.
Q. What is required to become a member of that organization?

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A. Again, those requirements are listed on the website and they -- it's a professional license or non- -- non-licensed individuals listed on the website.
Q. Okay. You're a member of Women Leading Healthcare; is that right?
A. Yes.
Q. When did you become a member of that organization?
A. 2020. Yeah. More recent.
Q. And what is required to become a member of Women Leading Healthcare?
A. Yes. That requires an appointment. You have to be invited to join by a current member.
Q. And whom were you invited by?
A. I was invited by a colleague who worked with me at the time.
Q. Worked with you at which of your --
A. At ARMSRx.
Q. You're also a member of Healthcare Businesswomen's Association?
A. Yes.
Q. When did you become a member?
A. I don't remember exactly the year.
Q. Do you remember approximately?
A. Maybe 2019, around that time.

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Q. Okay.
A. 2019.
Q. So recently, in the last few years?
A. Uh-huh.
Q. Okay. What is required to become a member of Healthcare Businesswomen's Association?
A. It would be -- again, it's listed on the website, all the criteria, but be in the healthcare field, be a woman in the healthcare field.
Q. You're also a member of the American Association of Consultant Pharmacists?
A. Correct.
Q. When did you become a member?
A. 2019 as well. 2018 perhaps. I don't remember exactly.
Q. Okay. What is required to become a member of that organization?
A. Again, those requirements are listed on the organization's site and among them include being a pharmacist in good standing.
Q. And, finally, you're a member of the American Society of Health Systems Pharmacists?
A. Correct.
Q. When did you become a member?
A. I initially became a member when I was in pharmacy school.
Q. Okay. And you're still a member today?
A. Correct.
Q. What is required to become a member of that organization?
A. It's listed on the site. A professional licensed or non-licensed individuals may join and they -- a pharmacist in good standing.
Q. Are you a member of any other professional organization besides the ones we've just discussed?
A. No.
Q. During your professional career, have you been a member of any other professional organization besides the ones we've just discussed?
A. No.
Q. Okay. And do you know whether there are any protocols, standards, or guidelines relating to the practice of pharmacy that are promulgated by any of these professional organizations?
A. Would you please restate the question?
Q. Sure. Why don't we start with the American College of Healthcare Executives. Does the American College of Healthcare Executives have any protocols, standards, or guidelines relating to the practice of pharmacy?

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A. No.
Q. Does the Academy of Managed Care Pharmacy have any protocols, standards, or guidelines relating to the practice of pharmacy?
A. Could you restate that question?
Q. Do you know whether the Academy of Managed Care Pharmacy has any guidelines relating to the practice of pharmacy?
A. Within the scope of managed care, they may provide recommendations or guidance.
Q. Are there any that -- that you are personally aware of?
A. As part of my role in my -- in my day-to-day functions, I review guidance and literature from these organizations and part of up -- keeping up with industry practice, and so it's always evolving, changing, and there's -- based on what's happening in the pharmacy practice and managed care world.
Q. Does the Women Leading Healthcare organization issue any guidelines, protocols, or standards with respect to the practice of pharmacy?
A. Not that I'm aware of.
Q. How about the Healthcare Businesswomen's Association?
A. Not that I am aware of.

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Q. Does the American Association of Consultant Pharmacists issue any guidelines relating to the practice of pharmacy?
A. No, not guidelines.
Q. Any protocols relating to the practice of pharmacy?
A. No.
Q. Any standards relating to the proto- -- to the practice of pharmacy?
A. No.
Q. Does the American Association of Consultant Pharmacists issue any sort of statements at all with respect to the practice of pharmacy?
A. Yes. They provide information with regards to consultant -- consulting pharmacy, yeah, so.
Q. What type of information?
A. Relevant to the field of consulting -- consultant pharmacists, and that could be all -- anything related to the pharmacy field.
Q. Is that in the nature of continuing education information?
A. They do have continuing education, yes.
Q. What other types of information?
A. Industry information, clinical information as it regards for consultant pharmacists. So anything tied into

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the pharmacy practice before consulting is -- could be on -- could be on their site or available.
Q. And does the American Society of Health System Pharmacists issue any protocol, standards, or guidelines relating to the practice of pharmacy?
A. Yes, they could.
Q. Are you personally aware of any protocols, standards, or guidelines that they've issued with respect to the practice of pharmacy?
A. They provide, you know, recommendations with regards to health system pharmacists and function within that capacity.
Q. Are you aware whether any of the professional organizations that you're a member of issue any protocol, standards, or guidelines with respect to litigation consulting?
A. No.
Q. No you're not aware or you know that they don't?
A. No, I'm not aware.
Q. Okay. And do you know whether any of the professional organizations that you're a member of issue any protocols, standards, or guidelines with respect to providing expert testimony?
A. No, I'm not aware.
Q. Okay. Have you ever engaged in any academic

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research regarding nitrosamines?
A. No.
Q. Have you ever engaged in any professional research regarding nitrosamines?
A. No.
Q. Have you ever published any articles relating to nitrosamines?
A. No.
Q. Have you ever published any articles addressing warranties?
A. No.
Q. Have you ever published any articles relating to Valsartan or Valsartan-containing drugs?
A. No.
Q. Have you ever published any articles relating to bioequivalence?
A. No.
Q. Have you ever published any articles relating to the FDA regulatory requirements that apply to pharmaceutical products?
A. No.
Q. Have you ever engaged in any academic or professional research relating to Valsartan or Valsartan-containing drugs?
MR. HANSEL: Object to the form.

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A. Could you restate the question, please?
BY MS. ISIDRO:
Q. Sure. Have you ever engaged in any academic research relating to Valsartan or Valsartan-containing drugs?
MR. HANSEL: Object to the form.
A. No.
BY MS. ISIDRO:
Q. Have you ever engaged in any professional research relating to Valsartan or Valsartan-containing drugs?
MR. HANSEL: Object to the form.
A. Could you be more specific?
BY MS. ISIDRO:
Q. Have you ever researched Valsartan in connection with your professional responsibilities?
A. Yes.
Q. In what context?
A. Again, I, in my role as a clinical pharmacist and consultant, I am staying, you know, up to date with all clinical information, pharmacy updates, medication updates, new to drug -- new to market generic brands, generic specialty, and so it -- I am knowledgeable on the drug.
Q. So when you say you're knowledgeable on the drug, what are you referring to?

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A. I understand what its intended use is for, what category, therapeutic category it's in, the -- its current -- its standing for inclusion in a formulary, and all components, you know, related to the medication in terms of formulary placement.
Q. Anything else?
MR. HANSEL: Object to the form.
A. Could you be more specific?
BY MS. ISIDRO:
Q. Have you conducted any research in Valsartan other -- on Valsartan other than the categories that you just mentioned?
A. No.
Q. Have you ever engaged in any academic or professional research regarding bioequivalence?
MR. HANSEL: Object to the form.
A. My education and my experience are -- involve those -- aspects of bioequivalence, and those are part of the components.
BY MS. ISIDRO:
Q. Sorry, part of the components of your education?
A. It's part of the curriculum in some way -- throughout the pharmacy program. So it is -- it's not unfamiliar to me.

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Q. Did you take any courses on bioequivalence during your pharmacy education?
A. Bioequivalence was incorporated into many courses within the pharmacy program as it relates to the medications we were studying at the time.
Q. So bioequivalence -- bioequivalence is a concept that you're familiar with from your education as a pharmacist, but you haven't taken any courses specifically on bioequivalence; is that correct?
MR. HANSEL: Object to the form.
A. The -- I completed all the coursework required for pharm- -- the pharmacy degree, both the bachelor's degree and the doctor of pharmacy degree and fulfilled all the requirements that those entail.
BY MS. ISIDRO:
Q. As you sit here today, you can't specifically recall whether that entailed a course specifically on bioequivalence?
MR. HANSEL: Object to the form.
A. Again, I completed all of the coursework required for a pharmacy degree and I fulfilled all the requirements for both bachelor's and doctorate of pharmacy degree, including licensure in the State of New York that -- I sufficed all of the academic requirements for all the classwork.

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BY MS. ISIDRO:
Q. As you sit here today, can you recall whether any of those requirements including a course specifically on bioequivalence?
MR. HANSEL: Object to the form.
A. No.
BY MS. ISIDRO:
Q. Have you ever authored any publications relating to epidemiology?
A. No.
Q. Have you published any -- withdrawn. Let me rephrase that.
Have you authored any publications in the last ten years?
A. No.
Q. Have you ever authored any publications?
A. No.
Q. Have you ever given any presentations relating to nitrosamines?
A. No.
Q. Have you ever given any presentations relating to product warranties?
MR. HANSEL: Object to the form.
A. I advise my clients on drugs standing -- approval standing, standing, and with regards to helping them with

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the formulary.
BY MS. ISIDRO:
Q. And how does that relate to product warranties?
A. That the drug is in good standing and meets the criteria for approval approved by the FDA.
Q. So you've never given a presentation, the focus of which is product warranties?
MR. HANSEL: Object to the form.
A. My professional capacity includes advising my clients and providing them guidance on -- on various drug products, structure of their prescription benefit program, and approvals and drugs in good standing for consideration on the formulary.
BY MS. ISIDRO:
Q. Okay. I'm not asking you though about your responsibilities in your client work. I'm asking about whether you have ever given a verbal presentation to a group of people with a topic focus on product warranties.
MR. HANSEL: Object to the form.
A. I have given a -- I have spoken to groups of people with regards to the promises that a -- a drug is listed to have or the approval that it has.
BY MS. ISIDRO:
Q. How many times have you given that presentation?
A. Many.

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Q. To whom?
A. To my clients.
Q. Your clients in connection with which of your jobs?
A. All of them.
Q. And do you have Power Points that you use for those presentations?
A. I have used Power Points.
Q. Do you keep those Power Points?
A. I share those with the clients.
Q. What have the titles of those presentations been?
A. Those are specific to the client and tied into their prescription benefit program.
Q. And has any of those presentations been specifically focused on the topic of product warranties?
MR. HANSEL: Object to the form.
A. Product warranties are the promises that products make for consideration for inclusion on the pharmacy formulary is a component of that discussion.
BY MS. ISIDRO:
Q. What do you understand by the term product warranties?
A. Product warranty is the promise that that product makes that it is safe and effective and meets the criteria for approval, as established by the FDA.

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Q. What is the basis of your understanding as to the meaning of the term product warranties?
A. The basis of my understanding pulls in my many years of education, my many years of experience in the pharmacy roles that I've held, and my many years of experience in my consulting role, providing guidance to clients about their prescription benefit program and all aspects related to that.
Q. Is it based on anything else or have we just fully discussed your basis for your understanding of that term?
A. I've provided you the basis for that.
THE WITNESS: May I take a break?
MR. HANSEL: Yes.
MS. ISIDRO: Sure.
THE WITNESS: Thank you.
THE VIDEOGRAPHER: The time is 10:49 a.m., and we're going off record.
(Break taken.)
THE VIDEOGRAPHER: The time is 11:08 a.m., and we're back on the record.
BY MS. ISIDRO:
Q. Dr. Panagos, outside of your client work, have you ever given any formal presentations on product warranties?

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A. I have given presentations on drug products that are approved for use by the FDA.
MS. ISIDRO: Sorry, can you read back my question, please?
(The requested portion was read back.)
MR. HANSEL: I object to the form of the question. Calls for a legal conclusion; asked and answered.
A. I have given presentations with regard to approved drug products for consideration on product formularies, pharmacy benefit programs.
BY MS. ISIDRO:
Q. So is that a no, outside of your client work you've never given formal presentations on product warranties?
MR. HANSEL: Object to the form.
A. I have spoken about drug products that are approved for use to individuals and groups outside of my client base as well.
BY MS. ISIDRO:
Q. And to whom have you given those presentations?
A. My patient to patient interactions, as well as my academic work with students.
Q. So you consider your patient to patient interactions to be formal presentations?

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A. The patient to patient ones are -- the one on one ones are not formal.
Q. Are you --
A. But they are a presentation to the patient about their drug.
Q. So when you refer to your patient to patient interactions, are you referring to any that are not one on one?
A. In that respect it would be members that are part of my client base. So it could be more than one.
Q. Sorry. We were talking about outside of your client base?
MR. HANSEL: Object to the form.
BY MS. ISIDRO:
Q. Isn't that right?
MR. HANSEL: Object to the form.
A. When consulting a patient regarding their medication it is pharmacist to patient.
BY MS. ISIDRO:
Q. Okay. And that's one on one?
A. Yes.
Q. Other than that, can you think of any formal presentations that you've given outside of your client work relating to -- to product warranties?
MR. HANSEL: Object to the form.

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A. The presentations that I have done are listed in my CV and what I've expressed to you just now.
BY MS. ISIDRO:
Q. Okay. So if it's not listed in your CV, you haven't given a formal presentation on it?
MR. HANSEL: Objection. That's not what she just said.
MS. ISIDRO: Can you read back the last response, please?
(The requested portion was read back.)
BY MS. ISIDRO:
Q. So am I understanding correctly that you have not given any formal presentations outside of what is listed in your CV?
MR. HANSEL: Object to the form.
A. No, that's not what I said. I said what is listed in my CV and what I have just expressed to you in terms of presentations to my clients regarding their drug product or prescription benefit program.
BY MS. ISIDRO:
Q. Okay. And outside of those two categories, there aren't any other formal presentations that you've given?
MR. HANSEL: Object to the form.
A. Formal presentations may include the work I did in academia with my students regarding drug products that

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are approved.
BY MS. ISIDRO:
Q. Have you ever taught a course relating to -- withdrawn.
What are the titles of the courses you've taught?
A. One of the --
MR. HANSEL: Objection: Asked and answered.
A. Pharmacy orientation is one course.
BY MS. ISIDRO:
Q. Any others?
A. The others were recitation courses and the department of social sciences and administrative services within the pharmacy program.
Q. What were the titles of those courses?
A. Those are listed in my CV.
Q. Can -- on which page?
A. Page 2.
Q. Can you show me where it lists the titles of the courses?
A. It lists that I was an adjunct assistant professor of pharmacy in the division of social and administrative sciences.
Q. So it doesn't list the titles of the courses that you taught in that role?
A. Correct. Those were recitation courses tied into

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the courses that fall under that division so.
Q. And what were the titles of you -- of the courses that you taught in that role?
A. I cannot recall at this time.
Q. Is there anywhere that you would be able to find that information?
A. Yes.
Q. Where?
A. In the records during my time there. It's information that I've had -- I had with respect to the courses.
Q. You say records of your time there. Are you referring to your personal records or the organization's records?
A. They would be in both.
Q. Now, looking at Page 3 of your CV, under communication, you state that you were a presenter PBMI Opioid epidemic, Health Underwriters organizations?
A. Correct.
Q. Can you describe what that refers to?
A. PBI (sic) is the Pharmacy Benefit Management Institute and they hold webinars of -- related to the profession and I was a presenter along with my colleague at the time for a presentation on the Opioid epidemic.
Q. When was that presentation?

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A. 2016.
Q. Do you still have the materials from that presentation?
A. No, I do not.
Q. Were you paid to give that presentation?
A. No, I was not.
Q. And was that presentation via webinar you said?
A. Yes.
Q. Do you know how many people attended that presentation?
A. No.
Q. Other than your pharmacy license in New York, do you hold any other professional licenses?
A. No.
Q. Have you ever had your license suspended?
A. No.
Q. Have you ever been punished or sanctioned in any way by a professional board?
A. No.
Q. Have you ever worked or consulted with FDA?
A. No.
Q. Do you hold yourself out as an FDA regulatory expert?
MR. HANSEL: Object to the form of the question.
A. I hold myself as an expert on what the FDA has

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approved for drug products, both brand and generics.
BY MS. ISIDRO:
Q. Do you hold yourself out as an expert on the process for approval of pharmaceutical products by the FDA?
MR. HANSEL: Object to the form.
A. I understand what the process entails by the FDA.
BY MS. ISIDRO:
Q. That wasn't my question. My question was do you hold yourself out as an expert on the process for approval of pharmaceutical products by the FDA?
MR. HANSEL: Objection.
A. Could you be more specific?
MR. HANSEL: Excuse me. Asked and answered and that's -- that's getting into a little bit of harassment territory. She answered the question.
MS. ISIDRO: I take issue with your characterization of that question as harassing. The witness is consistently failing to answer the question that is asked. This deposition is going to go for a really long time if that continues.
The witness is being asked a question. If she doesn't understand the question, she can let me know that she doesn't understand the question, but, otherwise, I expect the witness to answer the question that's been asked.

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Can you please read back the last question?
MR. HANSEL: Please also read back the answer when you do that.
(The requested portion was read back.)
A. The process for drug approval varies between brand and generics and I have an understanding of the process for -- for both of those drugs to be approved.
BY MS. ISIDRO:
Q. Is it your position that having an understanding of the process is all that it takes to be an expert on that process?
MR. HANSEL: Objection. Calls for a legal conclusion. Object to the form of the question.
A. I have been asked here today to render an opinion on what TPPs rely on when TPPs rely on or -- or consult when they're making -- with respect -- specifically to generic drugs for formulary decisions, and specific to generic drugs, that process involves an approval by the FDA tied to an ANDA application whereby the manufacturer has to meet the criteria for approval in order for that generic drug to gain their approval. That's what I've been asked to render an opinion on.
Was there something more you were looking for?
MS. ISIDRO: Can you read back the question and the answer, please?

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(The requested portion was read back.)
BY MS. ISIDRO:
Q. Dr. Panagos, are you offering any expert opinions in this litigation on the process for approval of pharmaceutical products by the FDA?
A. The process by -- for approval is established by the FDA --
Q. Doctor, I'm going to stop you right there.
MR. HANSEL: Excuse me. Let her finish her answer.
BY MS. ISIDRO:
Q. I'm asking you yes or no questions --
MR. HANSEL: Objection. No. You just interrupted the witness. That's unacceptable.
MS. ISIDRO: I am asking yes or no questions. You're making speaking objections, which are unacceptable.
MR. HONIK: Let's go off the record. This is Ruben Honik. Is the court reporter taking down my comment?
THE VIDEOGRAPHER: The time is 11:24. We're going off record.
(Off the record.)
MR. HANSEL: This is Greg Hansel. We're going back on the stenographic record. We are on the record

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stenographically.
On behalf of the Plaintiffs, we object pursuant to Federal Rule of Civil Procedure 30(d)(3), motion to terminate or limit which states in part: A, at any time during a deposition the deponent or a party may move to terminate or limit it on the ground that it is being conducted in bad faith or in a manner that unreasonably annoys, embarrasses, or oppresses the deponent or party.
On behalf of the Plaintiffs, Defendants have questioned Dr. Panagos for over two hours or approximately two hours on qualifications only. In addition to that, Defense counsel has repeatedly re-asked the same question on numerous occasions, in particular a question about whether the witness is qualified as an expert witness under federal procedure in effect. That question is a legal conclusion, calls for a legal conclusion. It's a question for the Court.
The witness is not an attorney. The witness does not know standards for acceptance of expert witnesses by federal courts under Daubert and other law. It is the parties, the Plaintiffs who have offered the expert, and even if the Defendants are not happy with the answer provided by the expert, that is not a

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ground to badger the witness, to repeatedly ask the question calling for a legal conclusion, and, in effect, harassing Dr. Panagos.

It's discourteous, it's not civil, and the Plaintiffs will not permit it to continue. We would like to request the Defendants for an offer of proof at this time of how much longer they intend to ask the witness about her qualifications and on which topics of her qualifications they intend to examine the witness.

We will consider that, and if it is unacceptable under Rule 30(d)(3), we will terminate the portion of the examination on qualifications to the extent only that we believe it is impermissible.

Is there anything else you'd like to add, Conlee, Charlie, Jorge?

MS. WHITELEY: No.

MR. HANSEL: Ruben? Anyone? Thank you.

MR. KERNER: The only thing I'd like to say is I would like an opportunity to confer with Defense counsel.

MR. HANSEL: Of course.

MR. KERNER: So we're going to need a couple of minutes.

MR. HANSEL: Sure. We'll step out.

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MR. KERNER: Yeah. I'd appreciate that.

(Break taken.)

MR. KERNER: And so we will respond to your statements earlier.

MS. ISIDRO: So, Counsel, I would like to state for the record that I categorically disagree with any suggestion that the questions that have been -- that have been asked here today are harassing or designed to embarrasses the witness in any way.

Unfortunately, the witness has repeatedly answered the question that she has wanted to answer rather than the question that has been asked.

In addition, there has been a pattern of speaking objections from Plaintiff's counsel, culminating in this inappropriate attempt to baselessly terminate or limit this deposition and to interfere with Defendant's rights to thoroughly explore the qualifications, as well as the -- the qualifications of the expert that Plaintiffs are offering, as well as the content and the bases for her opinions that she intends to offer in this litigation.

I note that you threatened to suspend the deposition of the witness after she was asked not a question about her qualifications but a question about whether she intended to offer specific opinions in

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this litigation. A yes or no question about whether she intended to offer specific opinions regarding the FDA process for drug approval in this litigation.

So, with that in mind, I would suggest that we continue with the deposition at this time, and as long as the witness answers the questions that have been asked, bearing in mind that you have an opportunity to Redirect after Defendants have asked their questions -- and so as long as she answers the questions that have been asked, I don't see any reason why there should be any problem continuing with the deposition at this time.

MS. WHITELEY: May I ask a question rather than -- do you have an amount of time that you have an idea of how long that you think it will continue on qualifications?

MS. ISIDRO: It should not be much longer, assuming the witness does answer the questions that have been asked. But if the witness continues to be evasive and, you know, we continue to have to ask the question ten different ways so that the original question can be answered by the witness, then it -- it will need to go much -- it will need to go longer and it's not on me to -- it's not within my power to be able to determine that. It's -- it's much more within

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the witness's power to determine how she's going to be answering questions.

MR. KERNER: Anybody else on the Defense side have anything that they want to add?

MR. GISLESON: Yeah. This is John Gisleson from Morgan Lewis on behalf of Aurobindo.

We do not believe that the questioning has been in any way inappropriate. The tone has been fair and balanced, and in our view the witness has been nonresponsive and evasive.

MR. KERNER: Anyone else on the Defense side?

The only thing I'll add is our intention is to move forward efficiently, to continue to ask appropriate questions, to continue to ask professionally, as counsel's been doing all morning, and to treat the witness with respect, as counsel has done all morning, and move forward with the deposition and get through it as quickly as we can.

There's no intent to keep this witness here one minute longer than necessary.

MR. HANSEL: Anything else from the Defendants?

MS. ISIDRO: Not at this time.

MR. HANSEL: All right. On behalf of the Plaintiffs, we disagree with your statements that the witness has been nonresponsive or evasive and we stand

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by our statements earlier, which I will not repeat.
Based on your representations, particularly to Attorney Whiteley's questions, that you intend to reach a conclusion to the questioning about qualifications with reasonable efficiency, we will allow the questioning of Dr. Panagos to continue now, including to a limited extent on qualifications, and I -- I guess if there's one thing I want to reiterate, it's that she is not -- we're not holding her out as an expert on Daubert and on what Federal Court standards are for the acceptance of expert witnesses, which is a legal question for the Court.
So, having said that, I will go get Dr. Panagos to -- to get started. Thank you.
MS. ISIDRO: Thank you.
(Off the record.)
THE VIDEOGRAPHER: The time is 12:17 p.m., and we are back on record.
BY MS. ISIDRO:
Q. Dr. Panagos, are you intending to offer any opinions in this litigation on the process for obtaining approvals from FDA for pharmaceutical products?
MR. HANSEL: Object to the form.
A. The process has already been established by the FDA for approval of drugs.

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Could you restate the question?
BY MS. ISIDRO:
Q. Are you intending to offer any opinions in this litigation on the process of obtaining approvals from FDA for generic pharmaceutical products?
MR. HANSEL: Object to the form.
A. I am rendering an opinion on what TPPs, third-party payers, rely on with respect to generic drugs for consideration to a drug formulary.
BY MS. ISIDRO:
Q. So you're not intending to offer any opinions on the process for obtaining approvals from FDA for generic pharmaceutical products?
MR. HANSEL: Object to the form: Asked and answered, argumentative.
A. The process for approval of generic drug products is already established by the FDA.
BY MS. ISIDRO:
Q. Would you defer to FDA on that process?
MR. HANSEL: Object to the form.
A. Would you please be more specific?
BY MS. ISIDRO:
Q. Would you defer to FDA with respect to matters involving the process for obtaining approvals for pharmaceutical products?

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MR. HANSEL: Object to the form.
A. As a pharmacist, I understand the process involved for approval of generic drug products as it entails how those decisions are tied into a formulary placement.
BY MS. ISIDRO:
Q. And will you be offering expert opinions in this litigation involving that process?
MR. HANSEL: Object to the form. Her report speaks for itself.
A. My expert opinion is what TPPs rely on and consider with respect to generic drugs for placement to the drug formulary.
BY MS. ISIDRO:
Q. That is the only category of information on which you intend to offer expert opinions in this litigation?
MR. HANSEL: Object to the form.
A. My expert opinion is on what TPPs rely on when consideration -- for consideration of generic drugs as -- for consideration to be placed on the formulary and it -- reimburse as part of prescription drug program.
BY MS. ISIDRO:
Q. That is the only category on which you are -- you will be opining in this litigation?
MR. HANSEL: I object to the form of the

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question.
BY MS. ISIDRO:
Q. You can answer.
A. As I understand your question, that is what my opinion will be rendered upon.
Q. Have you ever had any formal training in economics?
A. What do you mean by formal? Could you define that?
Q. Have you ever done any coursework in economics?
A. As part of my college degrees, some of the coursework entailed economics.
Q. Was that as part of one of your majors?
A. Yes.
Q. Which ones?
A. Biology and as well as pharmacy.
Q. Have you ever obtained any certifications in economics?
A. No.
Q. Have you ever obtained any degrees in economics?
A. No.
Q. Have you ever had any formal training in business principles?
A. Business coursework was also part of my college education.

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Q. In connection with which of your majors or minors?
A. Both biology, computer science, and pharmacy. So all -- all -- both majors and the minor.
Q. Outside of your college degrees, have you had any other coursework in business?
A. Only as it pertains to my continuing education credits for upholding my pharmacy degree, so business related to pharmacy continuing education.
Q. Have you received any certificates in business?
A. No.
Q. Have you received any degrees in business?
A. No.
Q. You are not a medical doctor, correct?
A. No.
Q. You're not a pharmacologist?
A. No.
Q. And you're not a toxicologist?
A. No.
Q. Aside from this litigation, have you ever been retained as an expert witness or an expert consultant in connection with litigation?
A. No.
Q. And you testified you've never been deposed before. Have you ever testified at trial

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before?
A. No.
Q. Have you ever done consulting work for any pharmaceutical company?
A. No.
Q. Have you ever done consulting work for any medical device company?
A. No.
Q. What percent of your income is currently derived from expert testimony or expert consulting in connection with litigation?
A. I have not calculated the percentage, but it's only with regards to the case I'm providing an expert report for here.
Q. Okay. Doctor, if we could turn back to Exhibit 1, which was your notice of deposition.
A. Uh-huh.
Q. You can pass Exhibit 2 back to me, just so you don't have too many papers in front of you.
MR. HANSEL: She may want to refer to the other exhibits.
MS. ISIDRO: Oh, certainly. If -- if you would like --
MR. HANSEL: If she could keep them there, I would appreciate it.

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BY MS. ISIDRO:
Q. If you'd like to refer back to them at any point, you're welcome to. I'm happy to take them back if it's too cluttered.
A. It's okay.
MR. HANSEL: Why don't you leave them nearby.
THE WITNESS: I'm fine.
MS. ISIDRO: Okay.
THE WITNESS: I'm good. Thank you.
BY MS. ISIDRO:
Q. Okay. And you're I believe still on Page 6, correct?
A. Correct. Uh-huh.
Q. Okay. Item Number 2 asks for articles, abstracts, studies, reports, et cetera, and am I understanding your testimony correct, you don't have any items responsive to Number 2?
MR. HANSEL: Excuse me. I'm going to object. I object to the form of the question because we've provided a written response as well.
A. Everything is included in my expert report, in my CV. All the materials necessary for this expert opinion that I'm providing are within the report and my CV.
BY MS. ISIDRO:
Q. Okay. But, Doctor, you've never authored any

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articles, correct?
A. Correct.
MR. HANSEL: Object to the form.
BY MS. ISIDRO:
Q. And you've never authored or co-authored any abstracts, correct?
A. Correct.
Q. And you've never authored or co-authored any published studies, correct?
A. Correct.
Q. You've never authored or co-authored any published reports, correct?
A. Correct.
Q. You've never authored or co-authored any publications, correct?
A. Right.
Q. Okay. You've never authored or co-authored any book chapters?
A. No.
Q. Or any books in their entirety, correct?
A. That is correct.
Q. Do you have in your possession, Doctor, any presentations -- withdrawn. Let me ask a different question.
Have you ever given any presentations or speeches

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regarding drug safety and cancer risk?
A. That's a broad question but I have spoken about drug safety and the potential for side effects or adverse effects as related to that drug. Those can include cancer.
Q. And in what context have -- have those speaking engagements been?
A. In every context as my professional -- in my professional career as a pharmacist. So in my current role, in my academic role, and in my previous roles in my -- with my previous employment.
Q. So has -- have those been specifically with and for your clients?
MR. HANSEL: Object to the form.
A. Primarily for my clients. But also for, if I was involved in a speaking engagement with my organization, it could have been to an audience that was not my client.
BY MS. ISIDRO:
Q. On how many occasions would you have spoken to an audience that went beyond your clients?
A. A few times a year. A few times a year, once a quarter maybe.
Q. During what time frame?
A. Again, it's been throughout my career. So I've been doing this work here now for 20 plus years and so it's been throughout my career, sometimes more, sometimes less.

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Q. What was most recent one?
A. The most recent engagement was to the Chicago Healthcare Underwriters speaking about pharmacy benefit programs.
Q. When was that?
A. That was, goodness, before COVID. So I'm trying to think of the date. I can't recall the exact date, but it was before the -- the COVID lockdown.
Q. Okay. And were you discussing cancer risk in connection with pharmaceutical products during that presentation?
A. We were discussing pharmacy benefit information, drug safety, drug formulary plan designs.
Q. So you don't specifically recall discussing cancer risk?
A. It was not the focus of the presentation.
Q. To the best of your recollection, was it discussed during the presentation?
A. Again, it was not the focus, but whenever you talk about a drug, you bring in I guess a clinical pharmacist for the side effects or adverse effects or any concerns.
Q. So it's possible that you may have discussed it, but you don't specifically recall discussing it; is that correct?

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A. Right. That was not the focus of the presentation.
Q. I understand you're saying it's not the focus and I just want to make sure that I'm understanding your answer.
A. Uh-huh.
Q. It was not the focus and you don't specifically recall discussing it, although it's possible you may have discussed it?
MR. HANSEL: Objection. I object to the form. Asked and answered, repeatedly.
BY MS. ISIDRO:
Q. Is that --
A. My --
Q. -- is my understanding correct?
A. My professional responsibility as a pharmacist when speaking about medications includes discussion of any potential concerns with the drug, including cancer, if it's relevant to the discussion. So I believe I'm answering your question.
Q. Okay. So I'll take that to mean that my understanding is correct and you may have discussed it but you don't specifically recall discussing it.
MR. HANSEL: Objection and move to strike. Object to the form.

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BY MS. ISIDRO:
Q. And please feel free to correct me if I'm wrong in my interpretation.
MR. HANSEL: Again, object to the form.
BY MS. ISIDRO:
Q. Am I correct that your -- that all of the materials that you have relied on in forming your opinions in this case have been listed in the attachments to -- to your report?
A. All the materials have been listed, yes, in the attachment.
Q. Okay. And let's go ahead and mark a copy of your report and its exhibits as Exhibit Number 3.
MS. ISIDRO: She just needs to mark it first. Sorry.
MR. HANSEL: Can I have a copy?
MS. ISIDRO: Oh, I have it here. Sorry about that.
MR. KERNER: Yeah.
MR. HANSEL: I'm sorry.
(Exhibit No. 3 was marked for identification.)
BY MS. ISIDRO:
Q. And, Doctor, if you could turn to exhibit -- excuse me, Appendix A --
A. Uh-huh.

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Q. -- attached to your report. If you could just take a moment to review that and confirm for me that that is a complete list of the materials that you have relied on in forming your opinions in connection with this litigation.

A. This is a list of my materials that I've reviewed. My expert opinion is based on my experience, my education, my day-to-day upkeep of my profession to stay up to date with what's happening, and -- and the materials that I've reviewed are included here.

Q. Okay. And as far as the materials that you've reviewed, Appendix B -- excuse me --

A. A.

Q. -- Appendix A to your report is a complete list of the materials you've reviewed in connection with this -- with your opinions in this litigation?

MR. HANSEL: Object to the form.

A. My day-to-day responsibilities include reviewing many pharmacy and industry articles, data, and information, but with regards to this expert opinion the materials that I reviewed are listed in Appendix A.

BY MS. ISIDRO:

Q. You haven't reviewed any medical records in connection with this litigation, correct?

MR. HANSEL: Object to the form.

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A. Would you please be more specific than medical records?

BY MS. ISIDRO:

Q. Have you -- I'll rephrase the question.

Have you reviewed any medical records pertaining to the Plaintiffs in this litigation?

A. No.

Q. Have you spoken to any of the Plaintiffs in this litigation?

A. No.

Q. Have you spoken to any of the other experts that Plaintiffs have disclosed in this litigation?

A. No.

Q. Have you issued any invoices in connection with your work in this litigation?

A. I will -- I have not issued any invoices, but I did receive a retainer at the onset.

Q. And what was the amount of the retainer that you received at -- at the outset?

A. $4,500.

Q. Has that retainer been -- let me rephrase that.

Have -- have there been amounts consumed from that retainer?

A. Are you asking if I've used the monies?

Q. No, Doctor.

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A. I mean, consumed is -- you've used the word consumed. I'm not --

Q. Doctor, have you been tracking your charges in connection with this litigation?

A. Yes. I keep a record of my -- the time I spend on this case. Absolutely.

Q. How do you track the time that you spend on this case?

A. I keep a record of the time I spent in my own personal file.

Q. Are they written notes? Do you use a program or an app to track your time? How exactly do you keep those records?

A. It's a combination of written and tracked through an Excel.

Q. An Excel spreadsheet that -- that you populate?

A. That's correct.

Q. Okay. What is your hourly -- what is the hourly rate at which you are being compensated in connection with this litigation?

A. The hourly rate for non-testifying work is $375 an hour and for testifying work it's $400 an hour.

Q. What is your arrangement with respect to the retainer? And I'll explain what I mean. Is it -- is it something that's just there to guarantee payment or is it

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something on which you collect your fees as they are incurred up to the extent of the retainer or a different arrangement with respect to the retainer?

A. The retainer was for my expert report.

Q. Okay. And have you calculated the total amount of fees that you have incurred based on your time spent and -- and your hourly rate, up until today?

A. I have kept a report of the time I've spent for this expert report and case and I have that -- I have that recordkeeping, if you will.

Q. What is the total number of non-testifying hours that you have spent to date on this litigation?

A. Approximately 50 to 60 hours.

Q. I'm sorry? I didn't hear you.

A. Fifty to -- about approximately fifty hours.

Q. Approximately 50 hours. So at your non-testifying rate of $375 an hour, that would be approximately $18,750 in fees in connection with your non-testifying work so far; is that right?

A. You calculated it so.

Q. So that exceeds the amount of -- of the retainer, correct?

A. Yes.

Q. Will that retainer remain in place and you will invoice Plaintiffs for the full amount of -- of the fees

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that you have incurred so far, or will you reduce the amount that you invoice by the amount of the retainer?
A. I will reduce it by the amount of the retainer.
Q. Okay. When were you first retained in connection with this litigation?
A. The exact date I'm -- I have to look at the exact date, but it was in October I want to say or maybe late September of '21.
Q. Who first contacted you in connection with this litigation?
A. Greg Hansel.
Q. Did you know Greg Hansel before he contacted you in connection with this litigation?
A. No.
Q. Do you know how you came to be contacted in connection with this litigation?
A. I was told it was through my LinkedIn profile.
Q. When you do issue an invoice in connection with your work in this litigation, who will you be sending that invoice to?
A. Preti Flaherty.
Q. I'm going to go ahead and mark this document as Exhibit 4.
(Exhibit No. 4 was marked for identification.)
Do you recognize this document, Doctor?

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A. Yes.
Q. And what is it?
A. It is the engagement letter.
Q. Your engagement letter in connection with this litigation?
A. Yes.
Q. All right. What materials did you initially review in connection with this litigation?
A. All of the materials I reviewed are in the appendix.
Q. Let me ask my question a different way.
Did you review any materials prior to making a determination as to whether or not you would agree to your engagement in connection with this litigation?
A. So, again, my day-to-day functions in my professional role include reviewing pharmacy literature and materials, industry relevant information so that I am aware of -- so I can best advise my clients in -- in my professional capacity so.
Q. In making a decision as to whether or not you would agree to be engaged in connection with this litigation, did you review any materials relating to the litigation itself?
A. No.
Q. Did you review any materials relating to the

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claims at issue in the litigation?
A. No.
Q. Has anyone assisted you in doing research or gathering information in connection with the opinions that you're offering in this litigation?
A. No.
Q. What were you asked to do when you were retained in connection with this litigation?
A. I would ask -- I was asked to render an opinion on what TPPs rely on when -- with respect to generic medications.
Q. Other than Plaintiff's counsel, have you spoken to anyone about this litigation?
A. No.
MS. ISIDRO: Counsel, I'm about to start getting into Dr. Panagos's report. Should we break for lunch at this time and -- and then come back or should we get started and break at a later time?
MR. HANSEL: Let's break.
MS. ISIDRO: Okay.
MR. KERNER: How long? What do you think?
THE VIDEOGRAPHER: The time is 12:53 p.m., and we are off record.
(Break taken.)
THE VIDEOGRAPHER: The time is 1:56 p.m., and we

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are back on the record.
BY MS. ISIDRO:
Q. Good afternoon, Dr. Panagos. Do you still have in front of you Exhibit Number 3, your report with its Appendixes?
A. I do.
Q. All right. We're going to spend some time going through your opinions as -- as stated in your report. So I'm going to have you turn to Page 2, and specifically the fourth section of your report in Paragraph 12, you don't have any opinions that are stated in the earlier parts of your report prior to this paragraph; is that correct?
A. Correct.
Q. In Paragraph 12 you state that in July 2018 the FDA announced a voluntary recall of Valsartan, including Valsartan-containing drugs, due to contaminants NDEA and NDMA. What is your basis for that statement?
A. That information is found on the FDA website.
Q. What do you understand the term contaminants to mean?
A. These contaminants were found in unacceptable levels and probable human carcinogens and do not belong in the medication.
Q. I want to make sure I understood your answer.
MS. ISIDRO: Can you read back the question and

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the answer for me, please?
(The requested portion was read back.)
BY MS. ISIDRO:
Q. Am I understanding you correctly that you understand the term contaminants to mean any substance that does not belong in the medication?
MR. HANSEL: Object to the form.
A. In the scope of this case, a -- the contaminant is a substance that was -- should not have been in the medication and not consistent with the referenced labeled product.
BY MS. ISIDRO:
Q. So that is how you are using the word contaminants in this report?
MR. HANSEL: Object to the form. Asked and answered.
A. I've answered the question.
BY MS. ISIDRO:
Q. I just want to make sure I'm understanding your answer.
MR. HANSEL: Object to form.
BY MS. ISIDRO:
Q. Have I stated that correctly?
MR. HANSEL: Object to form.
A. Please restate so I can be sure I -- I understand

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the way you restated it.
MS. ISIDRO: Can you read it back, please?
(The requested portion was read back.)
BY MS. ISIDRO:
Q. I just want to understand, Doctor, whether -- what you've discussed in that prior response is a description of how you personally are using the term contaminants in your report.
A. Uh-huh. So a contaminant is any substance that is in the medication that should not have been there, not consistent with the referenced label product, and inconsistent with the safety and efficacy of the referenced labeled product.
Q. Thank you. What are you relying on for purposes of your definition of contaminants?
A. My industry knowledge, my pharmacy background, my education, studies, and professional scope in my career.
Q. Anything else?
A. No.
Q. You're not relying on any specific FDA regulations for the purpose of that definition?
A. The scope of my career relies -- you know, involves referring to FDA information so.
Q. Are there specific FDA regulations that you are referring to in terms of your understanding of the

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definition of the term contaminants?
A. Specifically, no.
Q. In the next sentence you say these contaminants are probable human carcinogens according to the International Agency for Research on Cancer classification. Are -- so are you relying on IARC's classification in that statement?
A. Yes.
Q. Have you independently assessed the carcinogenicity of NDEA or NDMA?
A. Not independently.
Q. Are you relying on anything other than the IARC classification in making that statement in your report?
MR. HANSEL: Object to the form.
A. The IARC classification is public information which is what I relied on to make that statement.
BY MS. ISIDRO:
Q. Okay. And you didn't rely on anything else for purposes of that statement?
MR. HANSEL: Object to the form.
A. Yes.
BY MS. ISIDRO:
Q. Yes. I'm sorry, yes, that's correct?
A. Yes.
MR. HANSEL: Object to the form.

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BY MS. ISIDRO:
Q. Okay. Apart from any alleged presence of NDEA or NDMA in Valsartan-containing drugs, are you offering any criticism of Valsartan-containing drugs?
A. Valsartan -- as long as they're being used for their intended FDA labeled use, no.
Q. The next section, Section 5, talks about background on TPP pharmacy benefits and Paragraphs 14 through 18 specifically talk about TPPs; is that correct?
A. Yes.
Q. What are you relying on in making the statements that you make in Paragraphs 14 through 18 with respect to TPPs?
A. I'm relying on the information I've listed in Appendix A.
Q. Can we -- can you please look at that appendix and identify for me which of the items listed on Appendix A you're relying on for purposes of paragraphs 14 through 18 of your report?
A. Yeah. So I have listed in the appendix experts -- excerpts, excuse me, of data, MSP data --
Q. That's the one that says Detail Claim Report, HMO fields added, July 6, 2021?
A. Yes. And the other items would be the coordination of benefits, third-party liability.

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Q. Okay. That's further up on the list on Page 1 of Appendix A?
A. Yes.
Q. Okay. Anything else?
A. And then further down where it says MADA claims for the recalled Valsartan.
Q. Okay. That's the last item on -- on that page, MADA claims data for recalled Valsartan --
A. Yes.
Q. -- four spreadsheets?
A. Yes. And then on the next page there are additional items referenced, fourth and fifth down. The recall status of NDCs.
Q. So you mentioned fourth and fifth down. Is that MADA Third Party Payor Plaintiff's Fact Sheet, and MSP Third Party Payor Plaintiff's Fact Sheet?
A. Yeah.
Q. And then two down from that, was it the recall status of NDCs listed? Is that the one you referred to?
A. Uh-huh.
Q. Okay.
A. Yes.
Q. Anything else?
A. My own experience from being an expert in this field and consulting and knowing how these entities work.

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Q. Have we now discussed all of the bases for your statements in Paragraphs 14 through 18 --
MR. HANSEL: Object to the form.
BY MS. ISIDRO:
Q. -- of your report?
A. All of my materials reviewed are in the appendix, so for my -- for the entirety of my expert report. So I've answered your question, you know, to the best of my knowledge at this point, but I have -- I'd have to go back and study each of the items in the appendix very closely to ensure that I haven't missed a point in those sections, but for purposes of our discussion, I have pointed out those that I believe are relevant.
Q. All right. The next section of your report, Paragraphs 19 and 20, deals with PBMs; is that correct?
A. Right.
Q. And what did you rely on in formulating the statements that you've included on Paragraphs 19 and 20 of your report?
A. My professional experience, my pharmacy knowledge and education, and the materials in Appendix A.
Q. And with respect to the materials in Appendix A, which of the materials listed in Appendix A formed the basis for your statements in Paragraphs 19 and 20 of your report?

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A. The American Journal of Managed Care, ASHP, Coordination of Benefits, Formulary Development, The Journal of Managed Care, Drug -- Navigating Drug Formularies and Pharmacy Benefit Management, the Orange Book, Principles of a Sound Drug Formulary, and the U.S. Food and Drug Administration Development Approval Process.
Q. The next section of your report, Paragraphs 21 through 28, discusses prescription drug formularies; is that right?
A. Yes.
Q. What did you rely on in formulating the statements in paragraphs 21 through 28 of your report?
A. The same ones I gave you for PBM.
Q. Okay.
A. Including my knowledge, experience, and education in my professional capacity.
Q. Okay. And nothing additional with respect to Paragraphs 21 and 28, is that correct, as compared with Paragraphs 19 and 20?
A. Just whatever falls under the scope of my professional capacity and my day-to-day functions.
Q. And would you consider Paragraphs 14 through 28 to be background for your opinions in this litigation?
MR. HANSEL: Object to the form. Calls for a legal conclusion.

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A. Please repeat the question?
MS. ISIDRO: Could you read it back, please?
(The requested portion was read back.)
MR. HANSEL: Same objection.
A. They can serve as a background or they're information pertinent to the -- the opinion, relevant and pertinent.
BY MS. ISIDRO:
Q. In Paragraphs 29 to 32 you make various statements concerning the Orange Book, correct?
A. 29 through -- well, it goes beyond 32.
BY MS. ISIDRO:
Q. Okay.
A. But yes.
Q. Okay. You have a Section D in your report titled Orange Book and that goes 29 through 32; is that correct?
A. In Section D, yes.
Q. Okay. What is the Orange Book?
A. The Orange Book, also known as the Approved Drug Products with Therapeutic Equivalence Evaluation, is a list of FDA approved drug products and they're -- approved for marketing as -- in the United States as they're labeled -- as their label indication.
Q. Doctor, as part of what PBMs do, do PBMs develop formularies?

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A. Yes.
Q. In doing so, do TP -- excuse me. Withdrawn.
Do TPPs review and either adopt a formulary as is or do they customize the PBM formulary?
MR. HANSEL: Object to the form.
A. Could you be more specific?
BY MS. ISIDRO:
Q. What specificity are you looking for?
A. When you say customize.
Q. Do TPPs make any changes to the formularies that PBMs develop?
A. TPPs, they're prescription -- the prescription benefit design is up to the client and they're -- what's included or excluded in that benefit design can be tied into the formulary.
Q. Is it possible for a TPP to use its own P&T committee?
A. If they have a P&T committee.
Q. In fact, you note in your Footnote 2 of your report that in some cases the development and management of a drug formulary is done in-house where the TPP will use its own P&T committee and might consult with the PPM, correct?
A. If they have their own P&T committee.
Q. And you do state that in Footnote 2 of your

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report, correct?
A. I have agreed.
Q. Do you have any knowledge as to what share of the proposed TPP class members developed their own formularies versus using a formulary developed by a PBM?
A. No, I do not.
Q. Short of making an inquiry into each -- each TPP class members whose formulary included the at issue Valsartan, is there any way to tell whether it was the PBM or the TPP to decided whether Valsartan should be included?
A. No, I will not speculate.
Q. In Paragraph 25 of your report -- it's the bottom of Page 4 and top of Page 5.
A. Uh-huh.
Q. You mention that the P&T committee is required to base formulary decisions on scientific evidence, standards of practice, peer reviewed medical literature, accepted clinical practice guidelines, and other appropriate information.
What is other appropriate information?
A. Data specific to the drug they are reviewing. It could include clinical studies.
Q. Anything else?
A. Yes. It could include other items.
Q. Such as?

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A. Drug monographs, product labels, submitted applications for approval, status within the Orange Brook -- Book.
Q. Is cost a factor?
A. P&T committees make their decisions based on clinical merit.
Q. So in your -- the diagram that you include in Paragraph 28 in the fourth tier down --
A. Uh-huh.
Q. -- it's titled P&2 -- P&T review meetings. Do you see that?
A. Yes.
Q. It lists safety, efficacy, and cost. What does that refer to, that reference to cost there?
A. P&T committees make their decisions primarily based on clinical efficacy, ensuring that the drug that is going to be considered for placement on the formulary is safe and effective. Additional functions may include cost as it pertains to reimbursement of the claim.
Q. So that is one of the factors that can be considered via a P&T committee, correct?
A. The primary factors are based on clinical merit and not cost.
Q. So you would not consider cost a primary factor, correct?

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A. P&T committees are unbiased advisory boards reviewing drug information based on the clinical merit of the -- that's their primary function. Once that is completed, they can include costs or may -- may or may not include that as part of their discussion.
Q. Okay. And you did include it as part of the diagram in Paragraph 28?
A. Uh-huh.
Q. Correct?
A. Yes.
Q. At the bottom of that diagram, the very last tier of that diagram, you refer to relevant stakeholders. Who are those relevant stakeholders?
A. Whoever the entity is deciding on the formulary, whether to adopt that formulary as part of their prescription benefit.
Q. The Orange Book is published by the FDA, correct?
A. Correct.
Q. And the Orange Book lists drug products that are approved by FDA on the basis of safety and effectiveness; is that correct?
A. Correct.
Q. The Orange Book also contains therapeutic equivalence evaluations for approved generic prescription drug products; is that correct?

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A. Yes.
Q. Who makes those therapeutic equivalence evaluations?
A. The FDA.
Q. When a generic drug manufacturer files an ANDA, one of the things that they must demonstrate to FDA in that ANDA is bioequivalence, correct?
A. That was not within the scope of my report, but I understand that to be part of the requirement.
Q. Okay. So that consideration is -- is outside the scope of your report and your opinions in this litigation, correct?
MR. HANSEL: Object to the form.
A. As I said, it is part of the process for filing an ANDA or applying for ANDA.
MS. ISIDRO: Can you please read back the answer that mentioned outside of the scope of the report?
MR. HANSEL: And the question also.
MS. ISIDRO: Sure. Please.
(The requested portion was read back.)
BY MS. ISIDRO:
Q. For Section D of your report, Paragraphs 29 through 32, what did you rely on in formulating those paragraphs of your report?
A. FDA information.

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Q. Which specific FDA information?
A. On ANDA process, on NDA generic drugs.
Q. Would the FDA information that you relied on be listed in Appendix A of your report?
A. I believe it is listed at -- that's Page 2, U.S. Food and Drug Administration Development Approval Process.
Q. Okay. Anything else?
A. I relied on my knowledge and experience in the industry, knowing how the process works.
Q. Okay. Did you also rely on the Orange Book preface that's listed in your Appendix A?
A. Yes, I referenced the Orange Book.
Q. I'm sorry, I miss -- I think I misheard you. I thought the only item that you had mentioned from Appendix A was the U.S. Food and Drug Administration Development Approval process?
A. Clearly the Orange Book is listed in the Appendix A as well, so let me clarify and say that I referenced that in addition. I think that's --
Q. Okay.
A. -- quite obvious.
Q. So it would be those two items from Appendix A, correct?
A. In addition to my knowledge and experience, understanding how the process works.

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Q. Okay. But not any of the other items listed on Appendix A, other --
A. It could have been --
Q. -- than the two that we've discussed?
A. It could have been -- all of the items in the appendix can have played a role in forming the entirety of my discussion and expert opinion. That's why they're listed there.
Q. Okay. Did the MADA Third Party Payor Plaintiff's Fact Sheet form the basis for any of your -- any of the information stated in Paragraphs 29 through 32 of your report?
A. Not as it pertains to the explanation of the Orange Book, the description of the Orange Book.
Q. Is there another aspect to Paragraphs 29 through 32 that it does touch upon?
A. By it, you mean -- can you be more clear?
Q. The MADA Third Party Payor Plaintiff's Fact Sheet.
MR. HANSEL: Object to the form.
A. Could you please repeat the question?
MS. ISIDRO: Sorry, could you read the question? I think you were asking for the court reporter to read the question back.
(The requested portion was read back.)

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MS. ISIDRO: I'll restate the question.
BY MS. ISIDRO:
Q. Does the MADA Third Party Payor Plaintiff's Fact Sheet form the basis of any aspect of your statements in Paragraphs 29 through 32 of your report?
A. No. Not the basis.
Q. In Paragraphs 33 through 41 of your report, you discuss definitions and significance of therapeutic equivalence code; is that correct?
A. That is correct.
Q. What did you rely on in formulating your Paragraphs 33 through 41 of your report?
MR. HANSEL: Object to the form.
A. The FDA information on the Orange Book.
BY MS. ISIDRO:
Q. Uh-huh.
A. And the explanation of therapeutic equivalence codes, public information.
Q. And just to make sure I understand the explanation of therapeutic equivalence codes, do you mean within the Orange Book itself or are you referring to something different?
A. The TE codes or therapeutic equivalence codes are present in the Orange Book.
Q. Okay. So the -- so those are the -- that's what

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you're referring to?
A. As I understand your question, yes.
Q. Okay. In Paragraphs 42 and 43 you discuss criteria for entry into the Orange Book; is that correct?
A. Yes.
Q. What is the basis for your statements in Paragraphs 42 and 43?
A. The FDA process established for drugs seeking approval.
Q. Is that the last item listed on Appendix A of your report?
MR. HANSEL: Object to the form.
A. That has the FDA item on the -- on the appendix, yes, but as I said, all of the items in my appendix could've played a role in my -- all of my -- entirety of my expert opinion.
BY MS. ISIDRO:
Q. I was asking specifically the response you gave to the prior question.
MS. ISIDRO: So could you read it back, that prior question and answer?
(The requested portion was read back.)
MR. HANSEL: Object to the form.
BY MS. ISIDRO:
Q. So, Dr. Panagos, in that response when you said

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the FDA process established for drugs seeking approval, were you referring to the last item that's listed in the Appendix A of your report or were you referring to something else?
MR. HANSEL: Object to the form. Asked and answered repeatedly.
The -- the witness has testified numerous times about things she relied on for the entirety of her report, and this repeated attempt to pigeonhole her is just unfair and it -- could we stipulate that her previous testimony about what she's relied on for her entire report will apply to each question about what she relied on for a particular paragraph?
MS. ISIDRO: Let the record reflect that counsel is making an inappropriate speaking objection. Defendants are entitled to explore the basis for the statements and conclusions in Dr. Panagos's report as a proffered expert in this litigation.
MR. HANSEL: Will you stipulate?
MS. ISIDRO: So -- we will not stipulate to waive our rights to explore the basis for her statements and conclusions in her report.
MR. DORNER: Hello. This is Drew Dorner. ZHP will not stipulate either to your proposed stipulation.

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MS. ISIDRO: Could you please read back the last question before the speaking objection, and I don't believe there was an answer, but if there was please read that too.
(The requested portion was read back.)
MR. HANSEL: Object to the form.
A. You're referring to the Orange Book, the process by which a drug can gain approval and list -- to be listed in the Orange Book is public information on brand and generic drugs and the processing must follow as established by the FDA. It's an authoritative source.
BY MS. ISIDRO:
Q. So, Doctor, in making your statements in Paragraph 42 of your report, I understand your response to be that you have relied on the U.S. Food and Drug Administration Development Approval Process. Am I understanding that to be -- am I correctly understanding that to be one of the bases for your statement in Paragraph 42 of your report?
A. One of the bases.
Q. Okay. What are the other bases for your statement in Paragraph 42 of your report?
A. The Orange Book itself, my experience, education, and professional capacity and -- and -- and my day-to-day experience in this field.

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Q. Any other bases that you're relying on for your statements in Paragraph 42 of your report?
A. No.
Q. And what are you relying on for your statements in Paragraph 43 of your report?
A. The same.
Q. Okay. You state in Paragraph 44 that a generic drug is a copy of a branded drug in terms of dosage, administration, and performance. What is your basis for that statement?
A. My understanding of a generic drug from my education, my experience, and the information on -- in -- I've listed in Appendix A.
Q. And which of the items listed in Appendix A are you relying on for the statement that a generic drug is a copy of a branded drug in terms of dosage, administration, and performance?
A. All of the information except for the claims data.
Q. So that includes -- so you are relying for purposes of that statement on the MADA Third Party Player -- Third Party Payor Plaintiff's Fact Sheet?
A. No. I include that as part of the claim, so let me clarify.
Q. Okay.

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A. Not the Plaintiff Fact Sheet.
Q. Okay. Because you also have an item called MADA Claims Data for Recalled Valsartan.
A. Those go together.
Q. Okay. So you did not rely on that? You did not -- did you rely on the MSP Third Party Payor Plaintiff's Fact Sheet?
A. No.
Q. Okay. Other than those three items in Appendix A to your report, you relied on all of the other items for purposes of the statement that a generic drug is a copy of a branded drug in terms of dosage, administration, and performance?
A. Including my knowledge, education, all --
Q. Did --
A. -- and -- yeah.
Q. Did you rely on the FIN Declaration for purposes of that statement?
A. No.
Q. Okay. In Paragraph 44 you go on to say that generic drugs must be bioequivalent to the branded drug, meaning the generic drug will work the same way in the body and be as safe and effective as the brand name drug.
A. That is correct.
Q. What are you relying on in making that statement

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in Paragraph 44?
MR. HANSEL: Object to the form.
A. Relying on my education, my degrees, my licensure as a pharmacist. It's a critical component to performing my day-to-day functions and understanding that foundational component, what a generic drug is. So I -- I rely on my education and my experience and the items I've listed in the appendix.
BY MS. ISIDRO:
Q. What FDA regulation or regulations define the term bioequivalent?
A. I was not asked to study that, so -- so I'm not going to answer that at this time. I'd have to study the FDA regulations very closely to be able to give a thoughtful and complete answer to -- to that question.
Q. Paragraph 45 you state that the substitution of generic equivalents, drugs considered bioequivalent by FDA, are encouraged by PBMs to provide the best care at an affordable cost.
What is your basis for that statement?
MR. HANSEL: Object to the form.
A. The Orange Book lists drugs that are approved to their referenced listed drug product to be the same and effective and to be considered -- a consideration for the formulary. Those drugs are considered substitutable

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because they are deemed to be safe and effective. It is really -- the -- the foundation or the basis that determined whether a generic drug meets the criteria for inclusion on a -- for consideration on a formulary, they are listed in the Orange Book or not.
BY MS. ISIDRO:
Q. Is it specifically the FDA's therapeutic equivalence evaluation that -- that determines whether a generic equivalent can be substituted?
MR. HANSEL: Object to the form.
A. They must have an approved ANDA and have a therapeutic equivalence code assigned to the medication that allows them to be considered substitutable.
BY MS. ISIDRO:
Q. And which are the codes that allow them to be considered substitutable?
A. AB.
Q. You state in Paragraph 46 that TPPs and P&T committees expressly rely upon the manufacturer's compliance with all applicable standards, obligations, and regulations.
What is your basis for that statement in Paragraph 46?
MR. HANSEL: Object to the form.
A. The information presented to the FDA for approval

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by an ANDA application is presented by the manufacturer who is responsible for the information they provide.
BY MS. ISIDRO:
Q. And what is your answer based on?
MR. HANSEL: Object to the form.
A. The application is submitted by the manufacturer who is responsible for the information they provide the FDA to be considered for approval. That includes all aspects related to that application.
BY MS. ISIDRO:
Q. What is your support for that response?
MR. HANSEL: Object to the form.
A. Manufacturers are responsible for their medication. They're responsible for the quality control, ensuring that that medication is safe and effective to -- when they're applying for that approval -- seeking approval by the FDA. It's their responsibility to ensure that it's safe and effective.
BY MS. ISIDRO:
Q. Is that your own opinion?
MR. HANSEL: Object to the form.
A. In my professional capacity, that is what I believe to be correct.
BY MS. ISIDRO:
Q. Within Paragraph 46 of your report, what are you

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relying on in making a representation as to what TPPs expressly rely upon?
MR. HANSEL: Object to the form.
A. So 46 refers to the P&T committee, which the P&T committee will make the decision whether the drug will be considered for the formulary or not.
I don't understand your question if you're asking something else.
BY MS. ISIDRO:
Q. Sure. There's -- there's a statement in Paragraph 46 of your report that TPPs and P&T committees expressly rely upon the manufacturer's compliance with all applicable standards, obligations, and regulations.
A. Correct. Via the NDA. The manufacturer has to provide that information to the FDA via their ANDA application to be considered for approval and that's the information that's relied upon for the approval.
Q. Okay. And you say that that information is -- is expressly relied upon by the TPPs and the P&T committees, correct?
A. That information is relied upon as it's provided in their application submitted to the FDA for approval.
Q. But am I correct in saying that Paragraph 46 of your report states that that information is expressly relied upon by TPPs and P&T committees?

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A. It's relied upon in that it -- it's provided to the applic- -- in the application for approval.
Q. Okay. Do you see the word expressly in Paragraph 46 of your report?
A. Yes.
Q. What did you mean by the word expressly in Paragraph 46 of your report?
A. That it is -- that it is the responsibility of the manufacturer to provide all the information, in conjunction with their medication, seeking approval by the FDA. It is their responsibility to do that.
Q. And Paragraph 46 says that TPPs and P&T committees expressly rely, correct?
A. Right. Because the manufacturers are providing that information on their ANDA application seeking approval by the FDA.
Q. So am I not understanding your sentence in Paragraph 46 correctly, that the TPPs and the P&Ts are the ones who expressly rely upon the information you're referencing?
A. Once that medication is approved, because they have provided that -- the manufacturer has complied with all the requirements needed for approval, that medication is listed in the Orange Book as having complied and so they will -- that suffices the requirement for consideration to

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the formulary.
Q. Can you point to any document in which a TPP expressly relies upon the manufacturer's compliance with all applicable standards, obligations and regulations?
A. That is done via -- referencing the Orange Book and the approval status of the drugs.
Q. So when you say that they expressly rely upon that information, am I understanding correctly that what you mean by that statement is that they --
A. It is the responsibility of the manufacturer to provide that information on their drug application, follow the process established by the FDA for their drugs to be considered for approval in the United States and considered for coverage on the drug formulary.
MS. ISIDRO: Can you please read back the prior question and answer, not this one.
(The requested portion was read back.)
BY MS. ISIDRO:
Q. Can you point to any document in which a P&T committee expressly relies upon the manufacturer's compliance with all applicable standards, obligations, and regulations?
MR. HANSEL: Object to the form.
A. The Orange Book is a representation of a list of drugs approved safe and effective for use in the United

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States.
BY MS. ISIDRO:
Q. Is the Orange Book issued by P&T committees?
A. No. It's issued by the FDA.
Q. Right. So the P&T committee is not making any express statements in the Orange Book, correct?
A. No, they're not.
Q. Have you read the ANDA for any Valsartan-containing drug?
A. No.
Q. You state in Paragraph 47 that the AB rating in the FDA Orange Book based as it is on the generic drug manufacturer's ANDA represents a manufacturer's warranty to TPPs and P&T committees for placement on a prescription drug formulary.
What do you mean by the term warranty in Paragraph 47?
MR. HANSEL: Objection. Calls for a legal conclusion.
MS. ISIDRO: It's a term she's used in her report. I'm entitled to ask her what she means by it when she uses it in her report.
Can you please read back the question?
MR. HANSEL: Can we stipulate that every time you ask a question about warranty I'm making a continuing

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objection that it's -- I object to the form because it is calling for a legal conclusion? Will you stipulate to that continuing objection so I don't have to repeat myself every time you ask a question about warranty.

MS. ISIDRO: No. I will not stipulate to that unless she will withdraw the use of the term warranty from her report in which case I don't have to ask about it anymore.

ZOOM PARTICIPANT: There's a pending question. Does the witness remember the question?

MS. ISIDRO: I was just going to ask that it be read back, please.

THE WITNESS: Thank you.

ZOOM PARTICIPANT: Ask her if she remembers it and let her answer it. Do you remember the question?

THE WITNESS: I'd like for it to be read back.

ZOOM PARTICIPANT: Thank you.

THE WITNESS: Thank you.

(The requested portion was read back.)

MR. HANSEL: Object to the form.

A. The warranty represents their promise or assurance that their drug is safe and effective and equivalent to the referenced listed drug product; the same as the referenced listed drug product.

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BY MS. ISIDRO:

Q. When you use the term warranty in your report, do you understand that to be a legal term?

MR. HANSEL: Object to the form.

A. No. It's a term that refers to a promise, an assurance, a guarantee that that manufacturer has set forth.

BY MS. ISIDRO:

Q. What are you relying on in making the statements that you've made in Paragraph 47 of your report?

MR. HANSEL: Object to the form.

A. When an ANDA is approved, it means that the manufacturer has fulfilled the requirements, including safety and effectiveness, for their drug to be approved.

BY MS. ISIDRO:

Q. You reference -- you reference a document in Footnote 6 at the end of Paragraph 47?

A. Uh-huh.

Q. Is that correct?

A. Yes.

Q. Are you relying on that document for purposes of the statement that you've made in Paragraph 47 of your report?

MR. HANSEL: Object to the form.

A. Not exclusively.

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BY MS. ISIDRO:

Q. But does it form part of what you're relying on in making the statement in Paragraph 47 of your report?

A. It refers -- Footnote 6 refers to P&T committees. What manufacturers represent in their ANDA is -- when the ANDA's approved, it's -- it means that the manufacturer has sufficed and is compliant to receive approval of a medication deemed safe and effective.

Q. Why do you reference -- withdrawn.

Why did you include Footnote 6 on Paragraph 47?

A. As a reference for P&T committees.

Q. And what is the purpose of including that in Paragraph 47?

MR. HANSEL: Objection: Asked and answered.

A. ASHP or the guidelines that they -- or they're -- they're a respected industry organization, pharmacy organization that have credible information.

BY MS. ISIDRO:

Q. How does the document that is referenced in Footnote 6 relate to your statement in Paragraph 47 of your report?

MR. HANSEL: Object to the form. Asked and answered, repeatedly.

A. Again, when a manufacturer's ANDA's approved, it represents that they've met all the requirements needed for

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approval of that drug. That information is public information, industry accepted among professionals.

BY MS. ISIDRO:

Q. Does the document referenced in Footnote 6 mention warranties at all?

MR. HANSEL: Object to the form.

A. I don't recall.

BY MS. ISIDRO:

Q. Okay.

MS. ISIDRO: Can we mark this as Exhibit 5?

(Exhibit No. 5 was marked for identification.)

THE WITNESS: Thank you.

BY MS. ISIDRO:

Q. Doctor, you've just been handed Exhibit 5. Is that the document that's referenced in Footnote 6?

A. Yes.

Q. I'll give you a moment to look it over so that you can refresh your recollection as to whether that document mentions warranties at all.

MR. HANSEL: Objection. It takes more than a moment to determine whether a 12-paged document with 3 columns on each page contains a single word at least once.

MS. ISIDRO: I'll give her as much time as she needs.

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MR. HANSEL: Great.
THE WITNESS: Okay. What would you like me to answer?
BY MS. ISIDRO:
Q. Does Exhibit 5 discuss warranties at all?
A. Exhibit 5 discusses P&T committee's formulary systems process for the formulary system, which includes safe and effective medications, which safe and effective medications are the responsibility of the manufacturer to uphold as part of their application process in seeking approval, and then for review by a P&T committee and consideration for the formulary. Exhibit 5 speaks to all of that.
Q. But it doesn't speak to warranties, does it?
A. A warranty is the promise that that manufacturer makes to -- to the people, to the world that their drug is safe and effective. It is by that promise that they suffice in doing that, that they obtain approval by the FDA.
Q. Can you show me where Exhibit 5 discusses the promise that a manufacturer makes to the world?
A. If you're looking for those words verbatim, you would not find them, but --
Q. Okay.
A. -- if you are a clinical person or someone

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familiar with the ASHP or the formulary process, you would understand the process around brand and generic drug approvals, formulary process, P&T committees, this is what we do, and it is industry practice that the drug must meet safe and effective -- be in compliance in order to gain approval by the FDA. Drugs that are not FDA approved would never be part of a drug formulary.
Q. Okay. And even if not in those specific words, a promise that a manufacturer makes to the world, can you show me where in Exhibit 5 that concept is discussed?
A. Page 910 talks about evaluating medications for inclusion on the -- in the formulary. That entire section refers to the process by which evidence based data should be used as part of the process.
Let me go back over here. The section on P&T committee, the section on managing formulary systems, all of those sections include the process that is accepted for drugs that have -- that can be considered for formulary.
Q. Okay. Any other sections of Exhibit 5?
A. There is sections on Page 9 on -- Page 911, sorry, generic drugs, formulary exceptions, subformularies, therapeutic --
MR. MESTRE: Are you getting close to a moment where you can --
A. Yeah. I'll just finish this.

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The entire document is a well constructed document industry accepted by professionals as capturing the process for -- capturing the process for medication strategies, approvals, P&T functions, and placement on the formulary. It really is -- provides a lot of insight that the process is established and followed so that drugs can be considered on the formulary if they have obtained FDA approval by demonstrating that they are safe and effective and it's throughout the document that that can be picked up on.
BY MS. ISIDRO:
Q. And you cited Exhibit 5 as support for your statement in Paragraph 47 of your report, correct?
A. Yes.
MR. HANSEL: Take a break?
MS. ISIDRO: We can go ahead and take a break now.
THE VIDEOGRAPHER: The time is 3:09 p.m., and we are going off record.
(Break taken.)
THE VIDEOGRAPHER: The time is 3:21 p.m., and we are back on the record.
BY MS. ISIDRO:
Q. Doctor, in Paragraph 52 of your report, you state that manufacturers are responsible for understanding their

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processes which includes presenting the presence of unacceptable -- of unacceptable and impurities.
A. Right.
Q. What do you mean by the term impurities in that paragraph?
A. Any substance that does not belong in the medication.
Q. Do you understand -- let me rephrase that.
As you use them in your report, are the terms contaminants and impurities interchangeable?
A. They --
MR. HANSEL: Object to the form.
A. They could be.
BY MS. ISIDRO:
Q. But I -- I'd like to know, specifically as you've used them in your report, are you using the terms as interchangeable?
A. Impurities or contaminants are items or things present that should not be there and potentially dangerous, not safe, and not effective.
Q. In your report are you referring to different things when you use the term impurities than when you use the term contaminants?
A. Within the scope of this case and this report they can be looked at similar.

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Q. Is there any distinction to you in your use of the term impurities in your report versus your use of the term contaminants in your report?
A. No.
Q. Do you know whether FDA views the terms impurities and contaminants as interchangeable?
A. I do not know if they view them as interchangeable.
Q. Okay. What is your basis for the statement in Paragraph 52 that manufacturers are responsible for understanding their processes, which includes preventing the presence of unacceptable and impurities?
A. Manufacturers are the ones submitting their application requesting approval; therefore, they are responsible for all the information they provide within that application.
Q. And what are you relying on in stating that conclusion?
A. Manufacturers are submitting an ANDA in this -- in this case. They are requesting that approval. They are providing the information.
Q. So is that your personal opinion based on the fact that they're the ones submitting the information?
A. They are applying for approval, so they must adhere to the requirements set forth by the FDA in order to

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obtain that approval. So they must provide all of the information required. Manufacturers must provide that.
Q. Must provide all of the information required by --
A. Required for consideration for approval of their drug by the FDA, yes.
Q. And that is what you are relying on in stating -- let me rephrase.
And that is what you are relying on in making your statement in Paragraph 52?
A. I'm relying on the fact that manufacturers submit applications for drug approval. It's a common, known fact.
Q. Are you relying on any specific FDA regulations in making your statement in Paragraph 52?
A. I don't understand your question.
Q. Are there any specific FDA regulations that you're relying on in making your statement in Paragraph 52 of your report?
A. The FDA regulates that if a manufacturer is seeking approval of their drug, they must file -- if it's a generic drug, which we're talking about specifically, they must file an ANDA application and meet the requirements for approval.
Q. And is that a specific FDA regulation that you're referring to or is that your general understanding?

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A. That is the industry accepted understanding of what -- if a manufacturer is seeking approval of their drug, they must file an application with the FDA. In the case of a generic drug the application is called an ANDA and that is filed with the FDA by the manufacturer who is seeking approval of their drug. That application must meet the requirements set forth by the FDA to be compliant, safe, and effective.
Q. In Paragraph 55 you state that P&T committees and TPPs rely on an Orange Book listing that a manufacturer™s compliance means their drugs meet FDA regulations and as such are suitable for formulary placement and reimbursable under a prescription drug benefit plan.
What is the basis for this statement in Paragraph 55 of your report?
MR. HANSEL: Object to the form.
A. My education, experience, and familiarity with P&T committees.
BY MS. ISIDRO:
Q. Anything else?
MR. HANSEL: Object to the form.
A. I've answered the question.
BY MS. ISIDRO:
Q. Okay. So that is -- that is the only thing that you're relying on making your statement in Paragraph 55 of

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your report?
MR. HANSEL: Object to the form.
A. As it pertains to generic drugs, yes.
BY MS. ISIDRO:
Q. Okay. And as it pertains to brand drugs?
A. Brand drugs follow another process by the P&T committee which is not the scope of this opinion.
Q. Okay. So does Paragraph 55 refer to anything other than generic drugs, any other categories of drugs?
A. Again, the Orange Book lists drugs that are approved in the United States. That's -- also includes brand drugs as well as their generic approved drug product.
So to the extent that I understand your question, P&T committees and TPPs will rely on the information in part listed in the Orange Book that lists the approved medications approved by the FDA for sale in the United States or marketing in the United States.
Q. And are you relying on anything other than your education and experience in making that statement?
MR. HANSEL: Object to the form.
A. My experience with P&T committees. Again, my day-to-day functions are keeping knowledgeable with the industry practice, functions, drug information. That's all part of what I do so I'm comfortable with what's required or what components are essential.

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BY MS. ISIDRO:
Q. And that is what you are relying on in making your statements in Paragraph 55 of your report and nothing else?
MR. HANSEL: Object to the form.
A. If we're being specific on a generic drug, the -- they will -- P&T committees will look to the Orange Book for that substitutability rating. Once that rating is -- once that drug has established that classification, it can be considered for the formulary, if it has -- can -- it has met FDA approval and it, in terms of generic drugs, is really what the reference point is so.
BY MS. ISIDRO:
Q. Okay. And -- and what are you basing that answer on?
MR. HANSEL: Object to the form.
A. Understanding how P&T committees work --
BY MS. ISIDRO:
Q. Did --
A. -- when -- with regards to generic drugs.
Q. And the basis for that understanding?
MR. HANSEL: Object to the form.
A. My experience with P&T committees.
BY MS. ISIDRO:
Q. Anything else?

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MR. HANSEL: Object to the form.
A. My education, experience, knowledge.
BY MS. ISIDRO:
Q. Any specific documents or regulations?
A. I've listed all the documents I've reviewed in Appendix A.
Q. Are there any documents listed in Appendix A that you're relying on for purposes of the statement that you've made in Paragraph 55 of your report?
A. My entire report is based on all of the data and documents in Appendix A and in addition to my education and experience so.
Q. Well, Doctor, I think we've identified specific examples of paragraphs within your report that don't rely on every document listed in Appendix A, correct?
MR. HANSEL: Objection. Mischaracterizes previous testimony over and over again. Object to the form.
BY MS. ISIDRO:
Q. You can answer the question.
MR. HANSEL: Same objection.
A. Appendix A lists the documents, materials that I reviewed in putting together my expert opinion, a report. I've reviewed all of those documents and taken them into consideration for putting together my expert opinion,

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including my education and 20 plus years of experience within this industry, including familiarity and knowledge on P&T committees.
BY MS. ISIDRO:
Q. Paragraph 56 again uses the term warranties. Is your use of the term warranties in Paragraph 56 referring to the same thing that your use of the term warranty of Paragraph 47 of your report refers to?
MR. HANSEL: Object to the form.
A. Yes. It refers to the same.
BY MS. ISIDRO:
Q. Okay. What is the basis for your statement in Paragraph 56 of your report?
MR. HANSEL: Objection to form.
A. When a drug is placed on the formulary, it's met the -- it's met the approval criteria approved by the FDA, so it's met that requirement. It can be considered for placement on the formulary, and based on that consideration or inclusion on the formulary, third-party payors will reimburse that on -- for that drug because it is included on the formulary because it has met FDA approval for being safe and effective.
BY MS. ISIDRO:
Q. In Paragraph 57 you state in the case of Valsartan, including VCDs warranties by the manufacturers

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were false. What time frame are you referring to in that statement?
A. All of the time frame from which contaminants were found in the drug.
Q. And what was that time frame?
MR. HANSEL: Object to the form. Foundation. Beyond the scope of the report.
A. The time frame is beyond the scope of this report and any of the time that the contaminants were in the drug is -- you know, can be considered.
BY MS. ISIDRO:
Q. So in -- in formulating your opinions in this report, you didn't consider the time frame in which the purported contaminants were found; is that correct?
MR. HANSEL: Object to the form.
A. I'm not sure I understand your question. Could you rephrase that?
BY MS. ISIDRO:
Q. I'm just trying to understand your answer that the time frame is outside of the scope of the report.
A. I believe the time frame for the contaminants -- it's -- the time frame for the contaminants has been questioned as to when the original contaminants were there, how long they were there, length of time, and so on. So I cannot comment on -- on that, other than the fact that

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there were contaminants within the drug product.
Q. Do you know when presence of NDMA in Valsartan or any VCD was first reported?
A. When it was first reported? Can you be more specific? Reported by whom?
Q. By anyone.
A. Again, the time frame on -- I will not speculate on -- on that time frame. You're not being specific enough when you say anyone.
Q. When is the first report of NDMA in Valsartan or a VCD that you are aware of?
MR. HANSEL: Object to the form.
A. In our -- in my professional capacity, we -- the FDA had reported the contaminants to the world basically so.
BY MS. ISIDRO:
Q. When did that occur?
A. I believe it was 2018 or thereabout. I have to -- I'd have to go back and reference the exact date.
Q. Is that also the first report that you're aware of with respect to NDEA in Valsartan or VCDs?
MR. HANSEL: Object to the form.
A. Yeah. I can't speculate on those precise dates of those -- each of those components. I do know that they were present though in the medication.

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BY MS. ISIDRO:
Q. My question --
A. I believe the dates are irrelevant.
Q. Let me clarify my question because my question didn't refer to dates and wasn't calling for dates, so let me restate my question a different way.
You referenced a report by FDA to the industry or the world with respect to called contaminants in Valsartan or in VCDs, correct?
A. The FDA issued a recall. That's what I mean by report. They issued a recall on those drugs.
Q. Is it your understanding that the recall that you reference was initiated by FDA?
A. The FDA issued the recall. That's what I am attesting to. Who initiated the recall, again, what matters is the FDA issued the -- the recall.
Q. What do you mean by the term issued?
A. They provided the guidance that this recall is being set forth.
Q. What is your understanding -- or what is the basis for that statement?
A. Public information found on the FDA website.
Q. And the announcement of a recall was -- is that the first report that you're aware of with respect to presence of NDEA in Valsartan or VCDs?

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A. Yes.
Q. Do you know when FDA first set interim limits for nitrosamines?
A. No.
Q. Do you know when FDA first established guidance on control of nitrosamines?
A. Nope. That was not within the scope of my report.
Q. Okay. In Paragraph 59 of your report you state that the presence of the contaminant rendered the manufacturer Defendant's versions of VCDs not equivalent to the branded product.
What do you mean by the term contaminant in Paragraph 59?
MR. HANSEL: Object to the form. That doesn't read the entire sentence.
BY MS. ISIDRO:
Q. Would you prefer if I read the entire sentence, Dr. Panagos?
A. You don't have to.
Q. Okay. What did you mean by the term contaminant in Paragraph 59 of your report?
A. I referred to item present that should not have been present, not consistent with the reference listed drug product, and in this case unacceptable levels of a probable

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human carcinogen.
Q. Is there a specific probable human carcinogen that you are referring to?
A. The ones found within the drug that should not have been there.
Q. And which ones were those?
A. Both of the contaminants that are -- you've referenced.
Q. I'm sorry, I didn't reference any specific contaminants in my question.
A. You asked me about the contaminants in the previous question where you asked if I -- something about the FDA process around those.
So to the extent that I understand your question, I will answer and say that both of the contaminants in the case of these drugs represent a deviation from the reference listed drug product and not equivalent.
Q. Do you remember the names of those two contaminants that you're referring to in your response?
A. They are listed within my report in Section 4, Number 12. NDA- -- NDEA and NDMA.
Q. Okay. In Paragraph 59 of your report -- let me rephrase that.
What is the basis for your opinion that the presence of the contaminant rendered the manufacturer

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Defendant's versions of VCDs not equivalent to the branded product?
A. The contaminants were not in the branded product and therefore the generic drug could not have been equivalent to the branded product by the presence of the contaminants within the product, within the medication.
Q. In the first half of 2018 do you know whether the branded product was being tested for NDMA?
A. No. That was not within the scope of this report.
Q. In the first half of 2018 do you know whether the branded product was being tested for NDEA?
A. No. That was not within the scope of this report.
Q. At any point prior to 2018 do you know whether the branded product was being tested for NDMA?
A. Same response; not within the scope of this report.
Q. And at any point prior to 2018 do you know whether the branded product was being tested for NDEA?
A. Again, not within the scope of this report.
Q. Section 6 of your report you provide summary of your opinions; is that correct?
A. Yep.
Q. And Item B under this summary of opinions again

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mentions the term warranty. Is the term warranty being used in that item 6B in the same way as it is being used in Paragraph 47 of your report.
MR. HANSEL: Object to the form.
A. Yes.
BY MS. ISIDRO:
Q. In Item D under Section 6, you state that the generic manufacturer -- that -- excuse me. You state that if the generic manufacturer of product changes in any way from the original product on the ANDA approval, then this changed product is not the same as the brand name medication.
What is your basis for that statement in Item D under Section 6 of your report?
MR. HANSEL: Object to the form.
A. Any changes to a generic drug product should be reported to the FDA. The ANDA in -- in this case or the medications in this case with the contaminants inconsistent with the ANDA submitted for approval.
MS. ISIDRO: Can you read back that last sentence in the answer? I didn't hear the whole thing. I'm sorry.
(The requested portion was read back.)
BY MS. ISIDRO:
Q. Are ANDA holders permitted to make changes to

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their original ANDA submissions, if you know?
A. They must be reported to the FDA. Any changes must be reported to the FDA, submitted to the FDA.
Q. In the second part of Statement D under Section 6 of summary opinions, you state that equivalence is nulled and the generic manufacturer may no longer rely on the brand name drug label?
A. Right.
Q. What is the basis for that statement in Section 6D of your report?
A. Uh-huh. The two --
MR. HANSEL: Object to the form.
A. The generic drug label no longer is identical or matches the -- the brand drug label is -- is inaccurate and cannot be deemed equivalent, safe, or effective.
BY MS. ISIDRO:
Q. And what is your basis for that statement?
MR. HANSEL: Object to the form.
A. For a substitutability to be applied to a particular drug, they must demonstrate that they are safe and effective. Deviation from that would thereby not demonstrate that.
BY MS. ISIDRO:
Q. In Statement I under Section 6 you state that the warranty from manufacturers for this products -- for these

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products turned out to false. Is your use --
A. To be false. Yes.
Q. So it should say to be false there?
A. Uh-huh.
Q. Okay. Is your use of the term warranty here in this Statement 6I of your report, are you using that term warranty there in the same way -- let me rephrase that question.
Are you using the term warranty in Section 6I of your report in the same way that you're using it in Paragraph 47 of your report?
MR. HANSEL: Object to the form.
A. Yes.
BY MS. ISIDRO:
Q. What is your basis for the statement in Paragraph 6I of your report that the warranty from manufacturers for these products turned out to be false?
MR. HANSEL: Object to the form.
A. The presence of the contaminants in unacceptable levels of probable human carcinogens, misrepresented with inaccurate -- did not adhere to the promise they made, stating that their drug met the criteria set forth by the FDA for approval, which includes that to be that the drug is safe and effective and identical to the brand drug -- reference listed drug.

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BY MS. ISIDRO:
Q. You used the phrase unacceptable levels --
A. Uh-huh.
Q. -- in your response. What do you mean by unacceptable levels?
A. Unacceptable levels is a -- what the FDA referenced in referring to the contaminants, and I will -- I adhere to the terms that they use.
Q. And you say what -- what the FDA referenced. Where do you mean --
A. When they --
Q. -- that the FDA referenced that?
A. Sorry.
Q. If you could just let me finish my question. Sorry.
A. Uh-huh.
Q. Where are you referring to that the FDA referenced that?
A. On their website.
Q. In what context?
A. In the context of the recall.
Q. In the context of the recall. The 2018 recall?
A. The recall of Valsartan.
Q. You also state in Paragraph 6I of your report that TPPs paid for medications that they should not have

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based on the manufacturer's false representation?
A. That is correct.
Q. What is your basis for that statement?
MR. HANSEL: Object to the form.
A. Medication would not have been approved with the contaminant and it would not have been considered for an inclusion on a drug formulary and it would not have been reimbursed in any way by a TPP if it was not approved.
BY MS. ISIDRO:
Q. Okay. Is there anything else that you're basing the statement in Paragraph 6I, that TPPs paid for medications that they should not have based -- should not have based on the manufacturer's false representation?
MR. HANSEL: Object to the form.
A. TPPs should not have paid for contaminated medication.
BY MS. ISIDRO:
Q. What is your basis for that statement?
MR. HANSEL: Object to the form.
A. The presence of the contaminants within the medications.
BY MS. ISIDRO:
Q. Anything else?
A. My statement I -- is accurate the way it's written.

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Q. Are you aware that FDA has said patients taking prescription medications with potential nitrosamine impurities should not stop taking their medications?
MR. HANSEL: Object to the form.
A. I am aware.
BY MS. ISIDRO:
Q. Do you have any knowledge as to the levels of NDMA or NDEA that were found in any particular lot of Valsartan-containing drugs?
A. That was not within the scope of this report.
Q. So, no, you don't have any knowledge as to those levels?
MR. HANSEL: Object to the form.
A. The specific levels, no.
BY MS. ISIDRO:
Q. Do you know whether there were certain lots of recalled Valsartan that did not contain any detectable NDMA or NDEA?
MR. HANSEL: Object to the form.
A. Again, not within the scope of this report. I cannot speculate.
BY MS. ISIDRO:
Q. Okay. So you don't know one way or the other?
MR. HANSEL: Object to the form. Assumes facts not in evidence.

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A. I would have to review. I cannot speculate to that.
BY MS. ISIDRO:
Q. So because you're saying you cannot speculate, that means you don't know for a fact one way or the other, correct?
MR. HANSEL: Object to the form.
A. I'm not sure what you mean by one way or another. Could you clarify?
BY MS. ISIDRO:
Q. Do you know one way or another whether there were certain lots of recalled Valsartan that did not contain any detectable NDMA or NDEA?
A. No.
Q. Dr. Panagos, would you agree that the main criterion for the inclusion of any product in the Orange Book is that the product is the subject of an application with an approval that has not been withdrawn for safety or efficacy reasons?
A. Current approval, yes.
Q. And you would agree that FDA determines bioequivalence, correct?
A. It's one of the factors that they look for when evaluating drug applications.
Q. In order to -- in order for a prescription drug

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product to be considered bioequivalent to another drug product, FDA has to make that determination, correct?
A. It's part of the --
MR. HANSEL: Objection to form.
A. It's part of their consideration.
BY MS. ISIDRO:
Q. Is there any other entity that is tasked with determining bioequivalence for prescription drug products in the United States besides FDA?
A. Not to my knowledge.
Q. And FDA's determination as to bioequivalence is made individually for each manufacturer and each product, correct?
A. For each submitted application, each ANDA is evaluated individually.
Q. Okay. FDA may change a product's therapeutic equivalence rating if the circumstances giving rise to a violation call into question the agency's assessment of whether a product meets the criteria for therapeutic equivalence, correct?
A. Yes.
Q. During the time frame that -- let me rephrase that.
Prior to the Valsartan recall in 2018, FDA did not take any steps that would reflect a determination that

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the products were no longer therapeutically equivalent, correct?
A. Not to my knowledge.
Q. You didn't review bioequivalence studies for any manufacturer Defendant's Valsartan-containing products, did you?
A. No.
Q. Did you consult with any actual P&T committees about the inclusion of Valsartan on a formulary?
A. Could you be more specific?
Q. How do you mean?
A. Valsartan is a generic drug.
Q. Uh-huh.
A. It would meet criteria for inclusion on the formulary if it is approved by the FDA following an ANDA application that meets the criteria for approval set forth by the FDA which -- including safety and effectiveness.
Q. Have you personally consulted with any actual P&T committees about the inclusion of Valsartan on a formulary?
A. I'm going to ask you to specify on time frame.
Q. Ever.
A. Following the recall it is -- the -- P&T committees had to kind of create a strategy around how to move forward with that information as it pertains to their drug formularies, and on behalf of my clients I was -- it

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was important to me to know what their strategy was going to be.
Q. In coming up with your opinions in this litigation, did you consult with any P&T committees about the inclusion of Valsartan on a formulary?
A. No.
Q. And in coming up with your opinions in this litigation, did you consult with any P&T committee about its use of the Orange Book?
A. No. Because I -- I know that's what they use.
Q. And in coming up with your opinions in this litigation, did you consult with any TPPs about the inclusion of Valsartan on a formulary?
A. No.
Q. In coming up with your opinions in this litigation did you consult with any TPP about its use of the Orange Book?
MR. HANSEL: Object to form.
A. Let me clarify that TPPs and committees, it is industry practice that they refer to the authoritative source known as the Orange Book for substitutability, for a list of drugs that are approved by the FDA marketed in the United States.
This is an ongoing, continual process, and in my day-to-day functions in my role as a clinical pharmacist

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and a consultant, those are the responsibilities that are consistent in industry and what are adhered -- are adhered to.
BY MS. ISIDRO:
Q. In formulating your opinions in this litigation, did you consult with any TPP about its use of the Orange Book?
A. The use of the Orange Book is an established process that is widely accepted and respected. It is the source of truth in terms of approved products, approved by the FDA and substitutable. It is the source of truth. It is relied upon by P&T committees for their generic medications to be considered for inclusion on the formulary. That does not change.
Q. Dr. Panagos, at this time I'm not asking you about the basis of your opinions with respect to a TPP's use of the Orange Book in general. I am asking you whether, in formulating your opinions in this litigation, did you consult with any TPP about its use of the Orange Book?
A. No, I did not need to consult with them because I'm confident that is the process that is adhered to.
Q. Let's -- let's go ahead and take a break.
THE VIDEOGRAPHER: It's 4:10 p.m., and we're going off the record.

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(Break taken.)
THE VIDEOGRAPHER: It is 4:34 p.m., and we are back on the record.
MS. ISIDRO: Dr. Panagos, I may have some further follow-up for you at -- in a little bit, but I don't have any further questions for you right now.
As I mentioned previously, there are some folks on Zoom and I'm not sure whether any of them have any questions for you right now.
MR. GISLESON: Actually, I do have a few questions. Can you hear me?
MR. KERNER: We can.
THE WITNESS: Yes.
CROSS-EXAMINATION
BY MR. GISLESON:
Q. Hey, Doctor. My name is John Gisleson. I represent a manufacturer named Aurobindo. Have you heard of Aurobindo before?
A. Yes.
Q. And are you aware that Aurobindo is a manufacturer of Valsartan and Valsartan-containing drugs?
A. Yes, I'm aware.
Q. Did you become aware of any public information that certain batches of Aurobindo Valsartan or Valsartan-containing drugs contained nitrosamine?

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A. I was aware that there were contaminants within Valsartan products.
Q. Did you learn what those contaminants were?
A. The contaminants are referenced within my report, Section 4 --
Q. What was the name of the contaminants?
A. -- Page -- Section 4, excuse me, Page 2, Number 12, NDEA and NDMA.
Q. Before this lawsuit and you were hired as an expert, had you ever heard the word nitrosamine before?
A. Yes.
Q. In what context?
A. I am a New York State licensed pharmacist, clinical pharmacist, and in my role, my day-to-day functions, it is my responsibility to understand medications -- FDA medications, approved medications, and any concerns surrounding those medications is part of my responsibility.
Q. And how did you learn what nitrosamine are?
A. There is a component of toxicology that is included in our pharmacy education; however, that was -- that is not within the scope of my report or the opinion that I'm rendering here.
With regards --
Q. Do you know how nitrosamine perform --

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MR. HANSEL: Excuse me. Excuse me, Mr. Gisleson?
MR. GISLESON: Yes?
MR. HANSEL: Please let Dr. Panagos finish her answer. This is the second --
MR. GISLESON: I'm sorry. I thought she was finished.
MR. HANSEL: This is the second time you've interrupted her and perhaps there's a lag. So please give her a moment to make sure -- sometimes she thinks about her answer carefully before she's finished. Thank you.
MR. GISLESON: That's helpful. Thanks for letting me know.
BY MR. GISLESON:
Q. I'm sorry, you can continue.
A. I just want to make -- go back the original question.
THE WITNESS: Could you please restate his original question?
MR. HANSEL: And could you please restate her partial answer. Thank you.
(The requested portion was read back.)
A. Okay. So any time there is a contaminant or there is an issue with a medication, it is my responsibility to understand that as it pertains to the

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scope of my work and my responsibilities as a pharmacist and as a prescription -- a pharmacy benefit consultant. And so with regards to the generic drugs in this case, those contaminants should not have been there.
BY MR. GISLESON:
Q. When did you learn of the presence of nitrosamines in Valsartan-containing drugs?
A. When the FDA issued the recall.
Q. Do you know whether that became publicized in the third-party payor and PBM industries about the recall or voluntary recall of Valsartan-containing drugs?
A. Yes.
Q. Did you speak with different individuals in the industry about the recall?
A. Yes. As it pertains to my clients.
Q. Did you, personally, recommend that any of your clients remove a Valsartan-containing drug from their formulary because it was reported to have the presence of nitrosamines?
MR. HANSEL: Objection. This gets into a number of areas that I want to comment on. This is confidential and Dr. Panagos appears today in her capacity as an expert witness, not in her capacity as a senior vice president or executive vice president of ARMSRx, and to ask her about her advice to her

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confidential clients is outside the permitted scope of this examination.
BY MR. GISLESON:
Q. Can you identify any of the clients for whom you work pertaining to formulary issues?
A. I don't think I understand your question. Do you want me to --
Q. Do you consider all of your clients to be confidential?
A. Yes, I do.
Q. Is it correct that you can't identify then any client for whom you have done work concerning a formulary because you consider all of your clients to be confidential?
A. You have to rephrase that question. It did not make sense.
Q. Do you consider every single one of the clients for whom you have provided counseling on formulary issues to be confidential?
A. My clients that I provide consulting on, that information is confidential, but if you're -- so I'm not sure what you're asking exactly.
Q. Are there any clients that you can identify for whom you have provided consultation or advice concerning inclusion of drugs in a formulary?

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MR. HANSEL: Object to the form. Do you mean identify in her mind or --
MR. GISLESON: The names.
MR. HANSEL: -- or testify to because they're confidential -- you know, because they're not confidential?
MR. GISLESON: Correct.
BY MR. GISLESON:
Q. Are there any that you can identify that you do not consider to be confidential so that we can have an idea of the kinds of companies that you have counseled on formulary issues?
MR. HANSEL: Just on the confidentiality issue, she can testify about the kinds of companies.
BY MR. GISLESON:
Q. Can you identify any third-party payor for who you have -- for whom you have performed work?
MR. HANSEL: Object to the form.
A. My clients include self-insured employers, third-party payers. I've -- I've indicated those within my expert report.
BY MR. GISLESON:
Q. Can you identify any of them by name?
MR. HANSEL: Objection. Asked and answered. Confidential.

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A. That information is confidential and does -- isn't pertinent to -- or within the scope of this opinion.
BY MR. GISLESON:
Q. So you are -- are refusing to identify the names of any third-party payors in any prescription benefit management companies for whom you have done work; is that correct?
MR. HANSEL: Object to the form. It's not a refusal. She is bound by client confidentiality, so she is complying with her obligation to maintain client confidentiality.
She's not refusing to do anything, Counselor.
BY MR. GISLESON:
Q. You will not answer or identify the names of any of the TPPs or PBMs for whom you have done work because, in your view, you're bound by confidentiality agreements that prohibit you from identifying the names of those companies; is that right?
A. Yes. And I will respect those.
Q. Now, since the time that it became public that certain manufacturers of Valsartan-containing drugs found the presence of nitrosamines in certain batches of their products, are you aware of any TPP anywhere in the country that removed a drug manufacturer from its formulary based on recall?

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MR. HANSEL: Object to the form.
A. Based on the recall there were strategies put into place, thoughtful, careful strategies put into place with guidance from the FDA.
BY MR. GISLESON:
Q. Strategies to do what?
A. How to best manage the recall as it pertains to patients who were taking those drugs and the best way for -- you know, to handle that.
Q. Can you identify any TPP anywhere in the country that removed one of the Defendant's VCDs from their formulary because of the recall?
A. In which time frame?
Q. At any point after the recall was publicized.
A. That was not within the scope of this report. Again, strategies were put into place to efficiently manage the recall, ensure that patients are not hurt by that.
Q. Right. But this goes to your opinion that the manufacturer warranty for these VCDs was false. TPPs unjustly paid for medications for which they have not have paid.
A. Right.
Q. My question is: Can you identify any TPP anywhere in the country, in the United States, that removed one of the Defendant's products from its formulary

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following the recall?
A. Following the recall, there were strategies put in place that included those particular NDCs no longer being a part of the formulary.
Q. Were they removed formally from the formularies?
A. I cannot speculate. They -- they were just not -- they were blocked.
Q. Okay. So the question's specific. Can you identify any TPP anywhere in the country that, in fact, removed a manufacturer's VCD from its formulary following the recall?
A. I will go back and say that TPPs or PBMs blocked the -- the drugs that were contaminated. That time frame is some point after the recall, after sufficient or adequate strategy was put through to -- based on the recommendations and guidance of the FDA.
Q. What do you mean by blocked?
A. The claims were no longer being adjudicated.
Q. What do you mean by no longer adjudicated?
A. If a patient went to the pharmacy with an NDC -- with a drug that had an NDC -- for a drug that had an NDC that was a contaminated product, those NDCs would not process -- they would not process on the claim's adjudication so that -- because they were contaminated.
Q. So because the VCDs were blocked, at that point

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the TPP did not pay for any of the VCDs at that point? Strike that.
Because the NDC for the BDC was blocked, did that mean that the TPP did not pay for a prescription for that patient?
A. I cannot speculate and that was not within the scope of this report or the opinion that I'm rendering here today. I do know that the TPPs paid for contaminated products where they should not have because they were not safe and effective.
At -- after the FDA issued the recall, there had to be a careful, thoughtful strategy, there was guidance, and so I can't say with certainty that they didn't continue to pay for those claims.
Q. Well, based on your industry expertise, can you identify any TPP who, in fact, paid for a VCD that had the presence of nitrosamine?
MR. HANSEL: Object to the form. Beyond the scope of the report. Asked and answered.
BY MR. GISLESON:
Q. You can answer.
A. As part of my day-to-day responsibilities, I review claims data that consists of medications and -- including possibly these medications with the contaminants.
Q. Can you identify by name any TPP that paid for a

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VCD that had the presence of nitrosamine?
A. If a TPP had the generic drug on their formulary during the time frame for which the contaminants were found, they, in that entirety of that time frame, they essentially paid for something they should not have.
Q. Can you identify any TPP anywhere in the United States that sought a refund from a manufacturer as a result of a beneficiary consuming a VCD that contained a nitrosamine?
A. That's not within the scope of my report or opinion I've been asked to render.
Q. Can you identify any such TPP or PBM anywhere in the country who sought a refund because a patient consumed a VCD that had the presence of nitrosamine?
A. What do you mean by a refund?
Q. Said that they paid for a VCD for one of their beneficiaries and should not have because it contained nitrosamine?
MR. HANSEL: Objection. Calls for a legal conclusion.
A. I'll go back and say that TPPs paid for a drug that was placed on the formulary because it had sufficed the criteria for approval as set forth by the FDA, and, as such, paid for the claims for those drugs where they should not have.

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BY MR. GISLESON:
Q. Well, you say they shouldn't have, but my question is are you aware of any TPP anywhere in the United States that sought to be reimbursed from a manufacturer because the manufacturer's VCD contained nitrosamine?
MR. HANSEL: Objection: Calls for a legal conclusion.
A. It is my understanding that TPPs are -- were, from the economic standpoint, negatively affected by these -- payment of these drugs.
BY MR. GISLESON:
Q. Understanding. How?
A. They paid for the drugs during the time period for which they should not have because they were contaminated. That information is found within claims data.
Q. Can you identify a single TPP that sought a refund prior to this lawsuit being filed because it paid for a VCD consumed by a beneficiary that contained nitrosamine? And if you can't, that's fine. I'm just asking based on your industry experience and contacts if you're aware of any TPP that sought a refund.
A. I believe that information is within the complaint.
Q. And that's the only basis for that information

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that you have? None from your own personal experience?
A. That is correct.
Q. Now, you said that once the recall was announced, it was necessary for TPPs to manage how to respond to the recall; is that right?
A. They needed to understand the recall and then determine a strategy.
Q. Did you have an understanding as to what the strategies were that were implemented by TPPs as a result of the recall?
A. Based on FDA guidance.
Q. What do you mean?
A. The recommendations that FDA made as a response to the recall and the concern about the safety of the drug and how to handle that.
Q. Did you become aware that the FDA issued acceptable intake levels?
MR. HANSEL: Objection. Beyond the scope. Object to the form.
BY MR. GISLESON:
Q. You can answer.
A. The FDA commented that the recall was attributed to unacceptable levels of a probable human carcinogen within the medication.
Q. In your experience, did the third-party payors

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and the PBMs become aware that there were acceptable intake levels of nitrosamine impurities in Valsartan and Valsartan-containing drugs?
MR. HANSEL: Object to the form. Foundation. Object to the foundation.
A. Are you --
BY MR. GISLESON:
Q. Let me start over.
You communicate with TPPs, right?
A. Yes.
Q. And on and after the recall of Valsartan-containing drugs, you communicated with TPPs; is that correct?
A. Yes.
Q. Approximately how many different TPPs have you communicated with following the recall of the -- of the VCDs?
A. Not sure.
Q. Can you approximate in any way?
A. I do not wish to do that.
Q. Being conservative, is it more than a hundred?
A. No.
Q. Is it more than fifty?
A. No.
Q. Is it more than ten?

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A. No.
Q. So following the recall, is it more than -- strike that.
Is it more than five TPPs with whom you've had contact since the recall of -- of VCDs?
A. Again, my clients can include TPPs, self-insured employer groups. So I've been in contact -- I was in contact with all of them. I think the number is irrelevant.
Q. In your experience, you certainly advise all those different clients that there were acceptable intake levels for VCDs containing nitrosamines, right?
MR. HANSEL: Object to the form.
A. I advised the clients what the FDA set forth in terms of the recall, the strategy, their recommendation, and guidance.
BY MR. GISLESON:
Q. So understood then that for VCDs that contained nitrosamines within the acceptable intake level, that patients could continue to consume those VCDs, correct?
MR. HANSEL: Object to the form.
A. Those -- that drug is taken for cardiovascular issues, hypertension. A very serious health condition, one for which a patient has to be closely followed, monitored

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by their prescriber, and it is never advisable to abruptly stop a medication like that because of the critical nature for which it's used.
How to carefully mitigate the recall and the issues surrounding the recall at the time were of -- paramount of importance to my clients, and that's what I did.
BY MR. GISLESON:
Q. So what you're saying is that TPPs wanted to ensure the health and safety of their beneficiaries who needed to take VCDs, right?
MR. HANSEL: Objection. Mr. Gisleson, I'm going to cut off this line of questioning.
I object to the form. It is outside the scope of her report. You have asked about this issue 12 different Ways. The witness has attempted to be cooperative, even though testifying that it is outside the scope of her report.
The report does not get into this. You're asking about her professional activities for a company that is not the expert in this case. Dr. Panagos is appearing individually, not on behalf of her employer for whom she did that work. The work is also confidential. So we're going to need to move on to another topic.

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BY MR. GISLESON:
Q. You said that the manufacturer warranty for these VCDs was false. TPPs unjustly paid for medications for which they should not have paid. Based on your serving as an expert in this case, are you aware that there were TPPs who paid for medications containing nitrosamines because the patients needed those medications for health reasons?
A. I understand that there -- in the strategy, that some strategies that took place were advising patients never to abruptly stop their medication and to consult with their prescriber as to a suitable transition.
Q. Did different patients have different transition periods?
MR. HANSEL: Excuse me. Mr. Gisleson, I have really tried to accommodate your questioning. I know you're trying to tie it to the report. Asking about patients of her clients now is unacceptable.
MR. GISLESON: I'm not asking about her client's patients.
MR. HANSEL: Well, I'm going to instruct the witness not to answer any questions about the patients of her clients of ARMSRx, which is not the testifying entity here.
Do not answer any questions about patients of ARMSRx clients.

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BY MR. GISLESON:
Q. Well, Doctor, do you know anything about TPPs and how they managed for the recall who are not your clients?
A. In general TPPs were managing the recall in a -- in a way that would allow access. As I said before, we -- not -- access, ensuring that patients can have time frame to transition to a non-contaminated product.
Q. Over what time period did that transition occur, to your knowledge?
A. That's not within the scope of my report and that -- that's very patient specific information on how and when a patient consults with their prescriber and pharmacist in their individual case on how to transition to a non-contaminated FDA approved product.
Q. Do you know what the FDA definition of bioequivalence is?
MR. HANSEL: Objection. Asked and answered. This was gone over in great detail by Attorney Isidro.
MR. GISLESON: I don't think we got a clear answer to it.
BY MR. GISLESON:
Q. Do you know what the FDA definition is of bioequivalence?
MR. HANSEL: Object to the form.
A. Page 6, Section E under 33 has the definition for

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bioequivalent drug products.
BY MR. GISLESON:
Q. You looked at that definition before preparing your report?
MR. HANSEL: Object to the form. It's in the report.
A. I'm not --
BY MR. GISLESON:
Q. Did you ever have occasion before being retained as an expert in this case to look at the FDA definition of bioequivalence?
A. It's part of the scope of my profession.
Q. Pardon me?
A. It's within the scope of my profession as a pharmacist that bioequivalent is within that knowledge base.
Q. Right. But did you read the FDA definition of bioequivalence at any point before you became retained as an expert in this lawsuit?
A. Possibly. I read many, many data, information, articles, studies, part of what I do day-to-day. I mean.
Q. Do you have any personal experience with the manufacturing of pharmaceutical products?
A. No.
Q. You said in your report at Paragraph 46 TPPs and

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P&T committees expressly rely upon the manufacturers compliance with all applicable standards, obligations, and regulations. What actions, in your experience, do TPPs take to determine whether manufacturer's complied with applicable standards, obligations, and regulations?
A. They reference the Orange Book, that if a drug is listed in the Orange Book, it means that it has been assigned FDA approval, been given FDA approval, which means that they had sufficed -- fulfilled the requirements of the ANDA, which includes that their drug is safe and effective.
Q. Anything else?
A. If we're referring to generic drugs, this is the authoritative source.
Q. When did TPPs begin to implement a block on VCDs based on the recall?
MR. HANSEL: Objection. This is beyond the scope of her report. I permitted some questions about this. I believe you've beaten that horse pretty thoroughly. It's not part of her report, she's not being proffered as an expert on that issue, and I would just ask you to please move on.
MR. GISLESON: No. I haven't beaten this horse. I'm still riding it and it's still healthy and in good shape. This goes directly to her opinion that TPPs unjustly paid for medications which they should not

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have paid; if there was a block, they didn't pay.
BY MR. GISLESON:
Q. So do you have an understanding as to what period of time TPPs implemented blocks concerning VCDs that were found to have the presence of nitrosamines?
MR. HANSEL: Object to the form.
A. The strategy that TPPs put in place following the recall is not a universal strategy across all TPPs and how they did that and when they did that is very much within that entity and was -- is not within the scope of my report, nor what -- what I was asked to render an opinion on.
What I do attest to is that TPPs paid for the drugs that were contaminated, would not have been FDA approved with the contaminant because they would not have been the same as the referenced labeled drug. So it's really as simple as that.
BY MR. GISLESON:
Q. If someone wants to know what strategy a particular TPP followed in response to the recall of VCDs, it's necessary to ask that TPP?
MR. HANSEL: Object to the form. Again, this is outside the scope of her report.
BY MR. GISLESON:
Q. You can answer.

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A. I don't know that that would be public information, but if you were a member or a -- engaged with a TPP, I would -- that information would be available to you.
Q. Are you aware of any public documents that identify the different strategies that TPPs took in response to the VCD recall?
A. Public information?
Q. Yes.
A. No. The FDA offered guidance on the recall. That was public information.
MR. GISLESON: Those are the questions I have. Thank you very much for your time.
THE WITNESS: You're welcome.
MR. KERNER: Any other Defendants on the Zoom?
MR. GEOPPINGER: Yes. Yes. I just have a couple brief follow-up questions. I just want to clarify something for the record.
REDIRECT EXAMINATION
BY MR. GEOPPINGER:
Q. Good afternoon, Doctor. I know it's getting late, so I'll be brief. My name's Jeff Geoppinger. I represent AmeriSourceBergen.
Doctor, you would agree with me that the definition of bioequivalent can be found in the Code of

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Federal Regulations, correct?
MR. HANSEL: Object to the form.
A. The FDA, yes, does have a definition for bioequivalence.
BY MR. GEOPPINGER:
Q. And the FDA's definition is found in the code of federal regulations, correct?
A. Could you be more specific when you say federal regulations?
Q. The Code of Federal Regulations 21CFR of the FDA promulgates its regulations.
A. I did not review.
Q. Are you aware that the definition of bioequivalence is contained -- the FDA's definition is contained within the Code of Federal Regulations?
A. That was not within the scope of my report and I did not review that document, but it's my understanding though that it should be there but I did not review it. I cannot speculate.
Q. You did not review that definition prior to preparing your report, correct?
A. No. I reviewed the definition. I did not -- if you're referring to a particular document that's not consistent in my report, that's what I'm referring to.
Q. I'm sorry, I don't understand the answer.

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MR. HANSEL: Do you have a document you can show the witness to ask her if she reviewed it?
MR. GEOPPINGER: No.
BY MR. GEOPPINGER:
Q. My question is, Doctor, in a -- in the -- in the process of preparing your report, did you review the definition of bioequivalent contained within the Code of Federal Regulations?
A. Yes.
Q. Okay. On -- in -- a moment ago you referenced Paragraph 33 of your report when asked about that definition.
A. Uh-huh.
Q. Would you agree with me, Doctor, that the language in Paragraph 33 of your report is not the definition of bioequivalence from the Code of Federal Regulations?
A. No, I don't agree with you.
Q. Is it your testimony that the language in Paragraph 33 of your report is the definition of bioequivalence from the Code of Federal Regulations?
A. To my knowledge.
Q. Okay. When using the term bioequivalence in your report, did you intend to use it as it is defined by the FDA in the Code of Federal Regulations?

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MR. HANSEL: Object to the form. Calls for a legal conclusion. Beyond the scope.
A. I believe my definition in my report captures what a bioequivalent drug product -- captures the definition appropriately.
BY MR. GEOPPINGER:
Q. I will agree that Paragraph 33 of your report cites a therapeutic equivalence code from the Orange Book for bioequivalent drug products. My question is about the term bioequivalence as used in the CFR.
When you used the term bioequivalence in your report, are you using it as defined in the Code of Federal Regulations?
MR. HANSEL: I -- I object. It has -- there's no foundation.
A. Since I'm unclear of your question, I prefer not to answer.
BY MR. GEOPPINGER:
Q. I'll try to answer -- ask it again and make it more clear. When you used the word bioequivalence in your report, did you -- are you using it as it is defined by the Code of Federal Regulations?
MR. HANSEL: I -- I object. Mr. Geoppinger, are you asking the witness to assume that the word bioequivalent is only defined one time in the entire

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Code of Federal Regulations?
MR. GEOPPINGER: I'm not asking her to assume. I think she already testified that she's aware that the word is defined in the -- by the FDA in the Code of Federal Regulations.
A. I believe my definition captures what a bio- -- is accurate as to what a bioequivalent drug product is.
If you're asking if I've memorized the Federal Regulation's definition for bioequivalence word for word, that was -- that's -- I don't have that memorized word for word but I'm confident that my definition here captures the appropriate definition for bioequivalent drug product.
BY MR. GEOPPINGER:
Q. I'm not asking, Doctor, I'm not asking you if you've memorized it and I'm not asking about the -- the term bioequivalent drug products. That's not what I'm asking about.
I'm asking about the word bioequivalence.
MR. MESTRE: Can we get an update on the time, please?
BY MR. GEOPPINGER:
Q. Doctor, when you use the --
MR. HANSEL: Just a minute, Mr. Geoppinger. We're just doing a time check here.
MR. KERNER: You're also doing it while the

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question is pending.
MR. MESTRE: I just want to know the time, so we don't go over.
MR. GEOPPINGER: I'm sorry. I'm in the middle of my questions. Why do we need a time check?
MR. HANSEL: Well, not if the time's almost up.
MR. MESTRE: I just don't know.
MR. KERNER: Until she answers the questions rather than interrupting him in the middle of his examination.
MR. GEOPPINGER: Excuse me. I have a question pending. Is we -- are we still on the record?
MS. ISIDRO: We are.
MR. KERNER: Yes, we are.
MR. GEOPPINGER: Okay. Thank you.
BY MR. GEOPPINGER:
Q. Doctor, my -- my question -- I just want to clarify because I think we're missing each other here.
My question is about the term bioequivalence, not the term bioequivalent drug products.
MR. HANSEL: Excuse me, did you say bioequivalent with a T or bioequivalence with a C-E?
MR. GEOPPINGER: I'm talking about the word used on -- in Paragraph 59, the last word of that paragraph: B-I-O-E-Q-U-I-V-A-L-E-N-C-E,

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bioequivalence.
BY MR. GEOPPINGER:
Q. When you use that word, Doctor, in Paragraph 59, are you using it in the sense that it is defined in the -- in the Code of Federal Regulations?
MR. HANSEL: Object to the form. Foundation. You have not told her how it's defined in the Code of Federal Regulations. You have not shown her the purported definition in the vast Code of Federal Regulations to which you are alluding.
I object to the form of the question.
MR. GEOPPINGER: Counsel, I -- she's already testified she -- she's aware of the definition in the Code of Federal Regulations. Additionally --
MR. HANSEL: Well, you have represented that the definition that she used from the FDA Orange Book of bioequivalent drug products is not in the Code of Federal Regulations. There's no foundation here.
But please go ahead and answer, if you can.
THE WITNESS: Okay.
MR. KERNER: Now that you're done coaching the witness.
MR. GEOPPINGER: Yeah. Counsel, there's a deposition protocol, Counsel, and the Plaintiffs in this case have taken great issue with speaking

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objections. So I caution you that you should probably review that protocol and understand what the scope of your objections can be because that was way outside of the protocol here.

MR. HANSEL: I'm glad you brought that up. Part of the --

MR. KERNER: Why don't we let her answer this question?

MR. HANSEL: Part of the guidelines in this court are that follow-up questions such as yours, Mr. Geoppinger, are limited to questions not covered earlier or questions specific to a Defendant. Attorney Isidro covered bioequivalence extensively in her -- her examination and so I don't believe your questioning is within the permitted scope.

So please, please wrap it up.

BY MR. GEOPPINGER:

Q. Doctor, I'll ask the question hopefully for the last time.

A. Okay.

Q. When you use the word bioequivalence as it is written in -- as the last word of Paragraph 59 of your report, are you using that word as it is defined in the Code of Federal Regulations?

A. I am using that word in the context of sameness,

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that the generic drug was the same as the reference listed drug product for safety and effectiveness.

MR. MESTRE: So hold on. This should not be controversial now. There's no pending question. It's 5:30 in the afternoon. I'd like to know the amount of time that's left.

THE COURT REPORTER: Five hours seven minutes.

MR. MESTRE: Thank you.

BY MR. GEOPPINGER:

Q. Doctor, that's your definition of bioequivalence?

A. You asked me how I used it in the context of the sentence in Number 59 where it says the presence of the contaminant rendered the Manufacturer Defendants' versions of VCDs not equivalent to the branded product as indicated in the Orange Book which serves as the source of truth for bioequivalence and permits substitutability of the generic drug when it meets those -- that criteria.

The drug did -- that we're -- so it did not meet the criteria by presence of the contaminants, was not the same as the branded drug, would not have met FDA approval for bioequivalence, and not the same as the referenced listed product, would not have been listed in the Orange Book.

Q. Doctor, have you now told me how you've defined bioequivalence in your report?

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MR. HANSEL: Object to the form.

A. As it pertains to Number 59 which you specifically asked me about, I have answered your question.

MR. GEOPPINGER: Thank you, Doctor. I don't have any more questions.

MR. KERNER: Any other Defendants on the -- the Zoom have questions?

MR. HANSEL: Hearing none, it's -- do the Defendants have any further questions?

MS. ISIDRO: I have just a couple more questions.

RECROSS-EXAMINATION

BY MS. ISIDRO:

Q. Without identifying any names, are any of the TPPs who are involved in this litigation current clients of yours?

A. No.

Q. Without identifying any names, are any of the TPPs involved in this litigation former clients of yours?

A. No.

Q. And have you ever worked for any of the entities who are Defendants in this litigation?

A. No.

MS. ISIDRO: Any questions?

MR. HANSEL: Yes. Yes, I do. Are you finished?

MS. ISIDRO: For the moment, yes. I may have

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some follow-up after you.

MR. HANSEL: Okay. Thank you.

FURTHER DIRECT EXAMINATION

BY MR. HANSEL:

Q. Dr. Panagos, thank you for your patience on a long day. I have a few questions for you on behalf of the Plaintiffs.

You may recall that Mr. Gisleson asked you some questions regarding whether you were aware of any third-party payors in particular who -- who paid for contaminated Valsartan and who were seeking a refund. Before he asked you about that after the lawsuit was filed, he asked you about it in general.

Are you aware that Plaintiffs Maine Automobile Dealers Association Insurance Trust and MSP Recovery Series allege in the complaint that they or their assignors in the case of MSP paid for contaminated Valsartan?

MS. ISIDRO: Objection.

A. Yes. That's within the complaint.

BY MR. HANSEL:

Q. And in your report in Appendix A you list various materials you reviewed for your report, right?

A. Yes.

Q. And among those materials are four categories of materials that contain data showing payments by MADA and

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MSP and those are the MADA Third Party Payor Plaintiff's Fact Sheet, the MSP Third Party Payor Plaintiff's Facts Sheet --
MS. ISIDRO: Objection.
BY MR. HANSEL:
Q. -- the --
MR. KERNER: Objection. Leading.
MR. HANSEL: I'm not finished.
BY MR. HANSEL:
Q. -- the MADA claims data for recalled Valsartan, and excerpts from MSP data July 6th, 2021.
Did you -- did you review that data?
MS. ISIDRO: Objection.
A. Yes.
BY MR. HANSEL:
Q. Is that the type of data that you ordinarily review in the course of your professional career?
A. Yes, it is.
MR. KERNER: Hang on a second. There seems to be a bit of echo in the room now. If somebody who is on the Zoom could mute themselves, that would be helpful.
BY MR. HANSEL:
Q. Did that data show in the case of MADA that -- that it paid for contaminated lots of Valsartan that were subject to the contamination alleged in the complaint?

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ZOOM PARTICIPANT: Objection: Foundation.
A. The data showed that the claims -- there were paid claims.
BY MR. HANSEL:
Q. And did the -- did the MSP data show paid claims of MSP's assignors?
A. Yes.
Q. Do you understand that MSP's assignors are third-party payors?
A. Yes.
Q. Do you understand that MSP is an -- is an assignee of third-party payors for Valsartan?
A. Yes, I do.
Q. Do you understand that MSP is suing in its capacity as a holder of valid assignments of those -- of the claims of its assignors?
MS. ISIDRO: Objection.
ZOOM PARTICIPANT: Objection. Legal conclusion and leading.
A. Yes.
BY MR. HANSEL:
Q. And do you understand that MSP alleges in the complaint that it stands in the shoes in effect of its assignor TPPs?
MS. ISIDRO: Objection.

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A. Yes.
BY MR. HANSEL:
Q. Do you understand that the proposed third-party payor class consists of third-party payors as defined in Paragraph 14 of your report?
A. Yes.
Q. Specifically all third-party payors in the United States and its territories and possessions that, since at least January 1, 2012, to the present, paid any amount of money for Valsartan-containing drug, intended for personal or household use, that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose, Wholesaler, or Repackager/Relabeler Defendant.
MS. ISIDRO: Objection.
BY MR. HANSEL:
Q. Is that your understanding?
A. Yes.
Q. Do you understand that the proposed class so defined is in effect, at least in part, suing for a refund, the word used by Attorney Gisleson, suing for a refund, at least in part in this lawsuit?
A. Yes.
Q. Today you've heard a lot of questions and objections about whether certain topics were within the scope of your report. Do you remember that?

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A. Yes.
Q. Does your report set forth the scope of your report accurately?
A. Yes.
MS. ISIDRO: Objection.
MR. HANSEL: Let me take a short break and see if I have any more questions.
MR. KERNER: How long --
MR. HANSEL: Under five minutes.
THE VIDEOGRAPHER: The time is 5:33, and we're going off record.
(Break taken.)
THE VIDEOGRAPHER: The time is 5:38 p.m., and we're back on record.
MR. HANSEL: No further questions.
Thank you, Dr. Panagos.
THE WITNESS: You're welcome.
MR. KERNER: Anybody else on the phone?
MR. GISLESON: Yeah. Just a brief follow-up. This is John Gisleson again for Aurobindo.
FURTHER CROSS-EXAMINATION
BY MR. GISLESON:
Q. You were asked about the MADA, M-A-D-A, claims data. Do you have any understanding as to how MADA managed its beneficiaries' prescriptions following the VCD recall?

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A. The claims data demonstrates -- shows claims that were paid for.
Q. Do you know what strategy MADA followed in response to the VCD recall?
A. That was not within the scope of my review.
Q. Did you do any investigation to determine how MADA managed its patients, its beneficiaries' prescriptions following the VCD recall in connection with your review of the claims data?
A. I reviewed the claims data which showed that the claims were paid for. That's it.
Q. Did you seek to learn how MADA managed the recall of VCDs?
A. That's not within the scope of my -- of the opinion I was asked to render.
Q. So you didn't do it?
A. I do not wish to comment or speculate on the strategy that they took. I reviewed the claims data which showed that they paid for claims for those drugs.
Q. Do you know whether MADA at any point implemented a block concerning NDCs or VCDs that contained nitrosamine impurities?
A. I do not know.
Q. Pardon me?
A. I do not know.

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Q. And as to MSP's assignors, do you know whether -- strike that.
Did you do any investigation to determine how any of MSP's assignors managed the VCD recall -- recalls following the identification of nitrosamine impurities?
A. That was not within the scope of my report. I reviewed the claims data that -- that showed that they paid for the claims.
Q. So as a result of the work that you did in this case, you have no understanding as to how MSP's assignors managed the VCD recall following the discovery of nitrosamine impurities, correct?
MR. HANSEL: Object to the form. Outside the scope. Asked and answered.
MR. GISLESON: It hasn't been answered.
BY MR. GISLESON:
Q. You can answer the question, please.
MR. HANSEL: Same objection.
A. They were assigned claims data. I did not review any further assignments or agreements.
BY MR. GISLESON:
Q. Including any strategies that any of those assignors followed to manage the recalls, correct?
A. That was not in the scope of my review. I reviewed the claims data that shows that those claims were paid for.

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Q. Did you do any investigation to determine whether any of MSP's assignors, assignor TPPs, implemented blocks at any point concerning VCDs containing nitrosamine impurities?
MR. HANSEL: Asked and answered.
A. I was not asked to review their strategies. I reviewed the claims data.
BY MR. GISLESON:
Q. And as a result, you have no knowledge as to what those strategies were, correct?
MR. HANSEL: Objection.
A. That was not --
MR. HANSEL: Asked and answered. Object to the form. Repetitive.
MR. GISLESON: I'm just looking for a direct answer to a clear question.
MR. HANSEL: Your question assumes that whatever payment data she already told you she reviewed can be completely divorced from whatever their strategy is, since you brought it up.
BY MR. GISLESON:
Q. You can answer the question.
A. If and when they had a strategy, I was not a participant or have knowledge of what that was. I have

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reviewed the claims data that shows that the claims were paid for.
Q. Any other information than claims data?
MR. HANSEL: Objection. Asked and answered.
A. Could you be more specific?
BY MR. GISLESON:
Q. Sure. What was the information in the claims data that was important to you?
A. Claims data demonstrated that the plan paid a portion of the medication and the member paid a portion.
Q. Anything else?
A. Indicating that that was re- -- medication was reimbursed or plan paid for.
Q. Anything else?
MR. HANSEL: Object to the form.
A. I -- the claims data followed a standard claims data format, typical of what we see in the industry when you're reviewing claims.
BY MR. GISLESON:
Q. Did the claims data identify specific individual -- the names of specific individuals?
A. If you're asking in general if claims data can include those fields, those fields -- can you be more specific as to how you're asking the question and with which --

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Q. Sure. Did the claims data that you reviewed identify the names of the patients who consumed the VCDs?
A. Not that I recall, no.
Q. I'm sorry, no?
MR. HANSEL: Would you like the court reporter to read back the answer?
MR. GISLESON: I couldn't hear.
MR. HANSEL: Would the court reporter please read back the answer?
(The requested portion was read back.)
MR. GISLESON: Thank you very much.
Those are all the questions I have. Thank you for your time and your patience.
THE WITNESS: All right. Thank you.
MR. DORNER: I have questions within the scope of that.
FURTHER FURTHER DIRECT EXAMINATION
BY MR. DORNER:
Q. Doctor, my name is Drew Dorner. I'm here on behalf of CHP.
The claims data that you just referred to would only reflect costs associated with the transaction at the time of the adjudication of the claim; is that right?
MR. HANSEL: Object to the form. Lack of foundation.

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Mr. Dorner, do you have an exhibit?
MR. DORNER: The witness has seen the exhibits, the claims data that she's referring to that she's reviewed.
MR. HANSEL: Well, it's not an exhibit to this deposition.
MR. DORNER: I'm not making it an exhibit. I'd like an answer to my question.
A. I will answer generally that claims data that has a plan paid amount or claims data that it's at the point of adjudication.
BY MR. DORNER:
Q. Okay. And that only reflects some -- some of -- some amount of money that exchanges at the time of that adjudication, but not, for example, any payments that might be made to a TPP well before the adjudication or any payments that might be made to a TPP after the adjudication; is that accurate?
MR. HANSEL: Object to the form. Lack of foundation.
A. I'm not sure what you're asking.
BY MR. DORNER:
Q. Sure. If a member of a TPP makes a claim for a medication, it's your testimony that there is claims data associated with that that would be reflected in the TPP's

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records. Am I understanding that correctly?
A. Yes.
Q. Okay. Where the claims data reflect that particular claim, any amount of money associated with that transaction is -- it reflects only money exchanged at the time of that transaction, right?
A. It reflects the plan paid and any member paid amounts at the date of service.
Q. Okay. I understand. And so if either prior to or subsequent to the date of service some amount of money was also exchanged that is related to the -- indirectly or directly related to the claim, that would not be reflected in the particular set of claims data that you were referring to when you were talking with Mr. Gisleson; is that right?
MR. HANSEL: I object to the form of the question. Lack of foundation.
BY MR. DORNER:
Q. You can answer.
A. Could you be more specific when you say exchange of money before or following outside of a claims data?
Q. Sure. And let me give an example. In -- in some cases a PBM or a TPP might benefit from a rebate, for example, from a drug manufacturer; is that right?
MR. HANSEL: Objection. Objection. This is

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beyond the scope of her report.
MR. DORNER: Hold on. This is -- no. No. We're not getting into speaking objections. She asked for a specific example. I'm giving her one. All right. You can object to the form.
THE WITNESS: Okay.
MR. HANSEL: I object to the form. It's beyond the scope of her report. It has nothing to do with her report. Other experts are addressing this issue.
BY MR. DORNER:
Q. You can answer the question, ma'am.
A. The claims data reflects what the plan paid.
Q. On the date of service, right?
A. On the date of service.
Q. It would not reflect in the example that I gave something like a refund; is that right?
MR. HANSEL: Object to the form.
A. Are you referring -- your question is unclear. Are you referring to refund? You said rebate. I think you're --
BY MR. DORNER:
Q. Yeah. I -- I -- I caught the same error. So the example I gave was a rebate. I apologize. It wouldn't reflect a -- a rebate subsequent to the date of adjudication; is that right?

MR. HANSEL: Objection: Beyond the scope.
A. I've answered that the claims data represents what the plan paid at the date of service. That amount is found clearly within the claims data.
BY MR. DORNER:
Q. Well, I appreciate your answer, but I would like an answer to my question. My question was: The -- a subsequent rebate would not be reflected in the type of claims data that you were referring to in your prior testimony to Mr. Gisleson; is that accurate?
MR. HANSEL: Object to the form. Calls for speculation, beyond the scope, asked and answered, no foundation.
BY MR. DORNER:
Q. You can answer.
A. To the best of my knowledge, if a rebate applied to these type of drugs, it would not be within the claims data.
Q. And if there were similar payments, not necessarily rebates but things like governmental subsidies that might also be paid well after the date of adjudication, that also wouldn't be reflected in the claims data you were referring to; is that accurate?
MR. HANSEL: Object to the form. Lack of foundation, calls for speculation, beyond the scope of

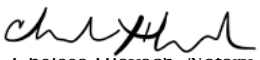
the report, asked and answered.
You need to wrap this up, Mr. Dorner. It has nothing to do with Dr. Panagos's report.
BY MR. DORNER:
Q. You can answer.
A. I don't know.
MR. DORNER: Okay. I have no further questions.
MR. KERNER: Anybody else on the Zoom?
MR. HANSEL: Anyone else in the room?
MS. ISIDRO: Nothing from me, no.
MR. HANSEL: We will read and sign.
Thank you very much, Dr. Panagos, and Chelsea, videographer, thanks very much, and for your hospitality, Jorge, thank you.
THE VIDEOGRAPHER: That concludes today's deposition. The time is 5:52 p.m., and we're going off record.
(The deposition concluded at 5:52 p.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA
COUNTY OF MIAMI-DADE

I, CHELSEA HLAVACH, shorthand reporter and Notary Public, State of Florida, certify that KALI PANAGOS, PHARM.D., R.PH, appeared before me and was duly sworn/affirmed Witness my hand and official seal this 21st day of January, 2022.

Witness my hand and official seal this 1st day of February, 2022.



Chelsea Hlavach, Notary Public
State of Florida, My Commission: GG352672, Expires: August 11, 2023

CERTIFICATE OF REPORTER

STATE OF FLORIDA
COUNTY OF MIAMI-DADE

I, CHELSEA HLAVACH, Shorthand Reporter and Notary Public, State of Florida, HEREBY CERTIFY that I was authorized to and did stenographically report the deposition of KALI PANAGOS, PHARM.D., R.PH; that a review of the transcript was requested; and the foregoing transcript, pages 10 through 199, inclusive, is a true and accurate record of my stenographic notes.
I FURTHER CERTIFY that I am not a relative, employee, attorney, or counsel to any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.
Dated this 21st day of January, 2022.

Chelsea Hlavach, Notary Public,
State of Florida at Large

GREGORY HANSEL, ESQUIRE
ghansel@preti.com

February 4, 2022

RE: In Re: Valsartan, Losartan, Et Al
1/21/2022, Kali Panagos, Pharm.D (#5024986)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at erratas-cs@veritext.com

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

In Re: Valsartan, Losartan, Et Al
Kali Panagos, Pharm.D (#5024986)

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Kali Panagos, Pharm.D Date

In Re: Valsartan, Losartan, Et Al
Kali Panagos, Pharm.D (#5024986)

ACKNOWLEDGEMENT OF DEPONENT

I, Kali Panagos, Pharm.D, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____
Kali Panagos, Pharm.D Date
*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS
_____ DAY OF _____, 20___.

_____
NOTARY PUBLIC

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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